



S U S T A I N

Final Report of the  
**Micronutrient  
Assessment  
Project**

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SUSTAIN's objective is to enhance the quality, safety, and availability of food in developing countries. In collaboration with the U.S. Agency for International Development (USAID), SUSTAIN provides access to specialized expertise in food science and technology to improve the level of nutrition in developing countries. The assistance is provided by experienced professionals from the U.S. food industry, who serve on a volunteer basis.

SUSTAIN's assistance is provided through assessments, technical assistance, and workshop training. To examine technical issues in more depth, SUSTAIN conducts scientific studies and organizes expert advisory panels, technical symposia, and technical publications. Depending on the nature of the request, SUSTAIN's assistance is provided either through long-term or short-term initiatives.

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## TABLE OF CONTENTS

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<b>EXECUTIVE SUMMARY.....</b>	<b>1</b>
<b>I. INTRODUCTION AND BACKGROUND.....</b>	<b>5</b>
<b>II. THE MICRONUTRIENT ASSESSMENT PROJECT.....</b>	<b>9</b>
A. Program Goal and Objectives	
B. Study Design	
<b>III. PROCEDURES AND METHODS.....</b>	<b>12</b>
A. Determination of Levels and Uniformity at the Production Plant	
B. Determination of Stability of Vitamins During Shipping and Storage	
C. Determination of Stability of Vitamins During Frozen Storage	
D. Determination of Stability of Vitamins During Food Preparation	
E. Analytical Testing Methods	
F. Statistical Analysis Methods	
<b>IV. FINDINGS AND CONCLUSIONS.....</b>	<b>20</b>
A. Micronutrient Levels During Production	
B. Micronutrient Uniformity at Production	
C. Stability of Micronutrients After Shipping and Storage of Commodities	
D. Stability of Selected Micronutrients During Food Preparation	
<b>V. RECOMMENDATIONS AND IMPLICATIONS.....</b>	<b>35</b>
A. Meeting Micronutrient Levels During Production	
B. Meeting Micronutrient Uniformity at Production Level	
C. Improving Stability of Added Vitamins	
<b>VI. ACCOMPLISHMENTS.....</b>	<b>42</b>
A. Improvements in Fortification at the Manufacturing Plants	
B. Contribution to Quality Assurance Procedures	
C. Enhanced Dialogue on Food Aid Commodities Initiated and Promoted Among Stakeholders	
D. Updating the Commodity Reference Guide (CRG)	
<b>REFERENCES.....</b>	<b>44</b>
<b>APPENDICES</b>	
A. Literature Review	
B. MAP Scope of Work	
C. Description of Analytical Methods	
D. Analytical Data, D.1-D.8	
E. Production Plant Data	
F. Companies Producing Fortified P.L. 480 Food Commodities and Vitamin/Mineral Premixes	
G. Composition of Vitamin and Mineral Premixes Used to Fortify Commodities	
H. Committees and Providers of Technical Assistance	
I. Advisory Details on P.L. 480 Program Foods	

## LIST OF TABLES

---

Table 1	P.L. 480 Title II Fortified Cereal Foods
Table 2	Micronutrient Standards for Fortified P.L. 480 Processed Cereals
Table 3	Micronutrient Addition Target Levels for Fortified Blended Foods
Table 4	Summary of Sub-Studies Performed on Fortified Foods
Table 5	Summary of Production Plants Sampled
Table 6	Recipient Sampling Sites
Table 7	Summary of Analytical Methods Used
Table 8	Summary of Problems of Selected Micronutrient Stability & Uniformity in Specific Food Aid Commodities
Table 9	Summary of Vitamin A Assays on FGIS Composite Lot Samples of Wheat Flour
Table 10	Summary of Vitamin A Assays on FGIS Composite Lot Samples of Bulgur
Table 11	Summary of Vitamin A Levels in Bulgur at Plant G
Table 12	Vitamin C and A Retention in CSB and WSB Based on Comparison of Mean Levels
Table 13	Vitamin C and A Retention in WSB Based on Comparison of Paired Samples
Table 14	Vitamin Retention in Frozen Samples
Table 15	Vitamin A Retention in Wheat Flour in Peru
Table 16	Vitamin A Retention in Wheat Flour in Bolivia
Table 17	Summary of Food Preparation Samples Collected in Selected Countries
Table 18	Vitamin A and Vitamin C Retention During Food Preparation
Table 19	Possible Minimum Levels of Possible Micronutrient Indicators for Processed Foods

## LIST OF FIGURES

Figure 1	Summary of Vitamin A Results from Production Plants
Figure 2	Summary of Vitamin C Results from Production Plants
Figure 3	Summary of Niacin Results from Production Plants
Figure 4	Summary of Iron Results from Production Plants

## LIST OF ABBREVIATIONS

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<b>ADRA</b>	Adventist Development and Relief Agency
<b>AOAC</b>	Association of Analytical Chemists
<b>AACC</b>	American Association of Cereal Chemists
<b>AV</b>	Analytical Variation
<b>BHA</b>	Butylated hydroxyanisole
<b>BHR</b>	Bureau for Humanitarian Response
<b>BHT</b>	Butylated hydroxytoluene
<b>CARE</b>	Cooperative for American Relief Everywhere
<b>CDC</b>	Centers for Disease Control
<b>CFSA</b>	USDA Consolidated Farm Service Agency
<b>CIN</b>	Committee on International Nutrition
<b>COV</b>	Coefficient of variation
<b>Cp</b>	Production capability
<b>Cpk</b>	Production capability index
<b>CRS</b>	Catholic Relief Services
<b>CSB</b>	Corn soy blend
<b>FDA</b>	Food and Drug Administration
<b>FFP</b>	Office of Food for Peace
<b>FGIS</b>	Federal Grain Inspection Service (also know as GIPSA, below)
<b>FHI</b>	Food for the Hungry
<b>GIPSA</b>	USDA Grain Inspection, Packers and Stockyards Administration
<b>HPLC</b>	High performance (pressure) liquid chromatograph
<b>KCCO</b>	Kansas City Commodity Office of the USDA, FSA
<b>MCH</b>	Maternal child health
<b>MT</b>	Metric ton = 1000 kilograms
<b>NAS</b>	National Academy of Sciences
<b>NAFTA</b>	North American Free Trade Agreement
<b>NGO</b>	Non-governmental organization
<b>OCF</b>	Other Child Feeding programs
<b>PVO</b>	Private voluntary organization
<b>P.L. 480</b>	Public Law 480
<b>RDI</b>	Recommended daily intake
<b>TCP</b>	Tricalcium phosphate
<b>SUSTAIN</b>	Sharing United States Technology to Aid in the Improvement of Nutrition
<b>TCP</b>	Tricalcium Phosphate
<b>TQSA</b>	Total Quality Systems Audit
<b>UNHCR</b>	United Nations High Commissioner for Refugees
<b>USAID</b>	United States Agency for International Development
<b>USDA</b>	United States Department of Agriculture
<b>WFP</b>	World Food Programme
<b>WSB</b>	Wheat soy blend



# EXECUTIVE SUMMARY

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## Background

The Micronutrient Assessment Project (MAP), a three-year scientific study on three continents, was launched in 1996 with funding from the United States Agency for International Development's (USAID) Bureau for Humanitarian Response, Office of Program, Planning, and Evaluation (BHR/PPE) with technical support from the Global Programs, Field Support and Research Bureau, Center for Population, Health and Nutrition, Office of Health and Nutrition (G/PHN/HN). This initiative was a result of increased attention in both Bureaus to the effective delivery of micronutrients (i.e., vitamins and minerals) to their target populations and to the shared concern that the impact be optimized. The MAP study was conducted by a team of food science and nutrition experts representing SUSTAIN (Sharing U.S. Technology to Aid in the Improvement of Nutrition), the Washington, D.C.-based nonprofit organization dedicated to improving nutrition and food quality worldwide. The goal of the MAP was to determine the level of micronutrients in the fortified food commodities provided in the United States (U.S.) P.L.480 food assistance program which reaches the mothers, children, and refugees targeted by emergency and development feeding programs in developing countries.

The USAID Office of Food for Peace administers the P.L. 480 Title II program, and through its partner organizations identifies recipient food needs. USDA procures the needed foods from U.S. producers and processors to be shipped in the form of Title II grants. In fiscal year (FY) 1998, under the Food for Peace Program, the U.S. donated more than 1.6 million metric tons of food commodities, reaching 43 million people in 53 countries worldwide. U.S. fortified food aid commodities have the potential to deliver micronutrients to the majority of these people. Over one-third of all FY 1998 Title II food aid, or 590,000 metric tons, worth \$183 million, consisted of micronutrient-fortified cereals.

The MAP investigated the stability (from production to consumption) and uniformity in the manufacturing process of key micronutrients added to processed Title II food commodities. It focused on vitamin A, niacin, and the mineral iron, tracking the levels of these nutrients at both ends of the supply chain, from U.S. manufacturer to overseas consumer. Of the several vitamins added to processed foods, vitamin A was selected for intensive study because of its significant health benefits, its relatively high cost when added as a fortificant and the challenge posed by the labile nature of this vitamin. Among other things, vitamin A plays an important role in maintaining eyesight and a strong immune system. Vitamin A deficiency (VAD) is a chronic, preventable problem, affecting 40 million and blinding over one million annually. The U.S. is part of a global effort to eliminate vitamin A deficiency and significantly reduce hunger early in the 21<sup>st</sup> Century. As a result, fortifying food aid commodities with vitamin A and eliminating the deficiency has become a high priority for the U.S. Congress, USAID, and other development/health organizations and nations worldwide. Iron and niacin, both of which are relatively stable micronutrients, were also chosen for their health benefits but also because of their potential use as "indicators" in quality assurance tests for fortification processes in the future. Though not part of the MAP study, the vitamin C results reported here were investigated by the SUSTAIN study team in a parallel activity supported by a separate cooperative agreement with USAID/G/PHN/HN. Vitamin C, like vitamin A, is a labile and expensive fortificant and therefore subject to the same questions regarding cost-effectiveness and potential loss during shipping, storage, and cooking. These issues, coupled with vitamin C's significant health benefits (e.g., fighting infection, aiding in iron absorption) sparked special interest in Congress.

In 1997 and 1998, the MAP, in conjunction with the vitamin C pilot program, sampled fortified blended and processed P.L. 480 cereals at delivery sites in Bolivia, Haiti, India, Peru and Tanzania to determine the stability of vitamins A and C during shipping and storage. The MAP team sampled blended food commodities, corn soy blend (CSB) and wheat soy blend (WSB) – before and after cooking – in Haiti and Tanzania and had them tested to determine vitamin retention during normal food preparation. Two models were used for studying vitamin stability: in the first, certain fortified batches of CSB and WSB were manufactured specifically for the MAP and followed to Haiti, India, and Tanzania; in the second, bulgur and wheat flour from lots/batches fortified and sampled in the normal manufacture process were collected by the MAP team for laboratory analysis. The lots then followed their normal path to Bolivia and Peru where they were sampled and tested again for vitamin A level after shipping and storage. The team also directly sampled and tested levels and uniformity of vitamin A, niacin, and iron at eight U.S. manufacturing plants involved in P.L. 480 commodity fortification, and tested vitamin A levels in official USDA

samples of bulgur and wheat flour from six other plants. A comparison of these samples to the samples taken at warehouses and delivery sites provided the basis for the vitamin A stability studies.

## Results

**Production Level Concerns:** SUSTAIN's study team uncovered serious shortcomings in the fortification of some P.L. 480 processed and blended cereals, particularly in the levels of vitamin A. The MAP visited eight production facilities and analyzed samples from over 12 plants and 25 production runs. MAP scientists directly sampled and tested food aid samples from five of the six U.S. manufacturing plants producing CSB, one of the two producing WSB, both plants producing bulgur wheat products, and several plants producing wheat flour. At the time of testing, problems were found in the processing of large and small manufacturers alike and ranged from low levels at manufacture to variable levels in the same production lot (i.e., lack of uniformity in processing). One producer had persistently low vitamin A levels at manufacture with many products containing as little as one-quarter of USDA-specified vitamin A levels for these fortified, processed food aid commodities. Three of the eight mills directly sampled by MAP during production were below target levels for vitamin A, two significantly (57% and 60% of target) and one moderately (70% of target). Composite lot samples provided by USDA showed similar concerns in six of ten wheat flour production runs sampled. The causes of these losses may include (1) poor quality vitamin A which is destroyed upon exposure to air during the production process; (2) low levels of the vitamin being added and; (3) separation of the vitamin from the commodity during production. Of the nine production runs directly sampled in this study, four showed problems in uniformity and/or meeting the minimum standards or targets for micronutrients. Reasons for this included faulty feeders, inadequate operating procedures or poor plant design. Products from these plants would not consistently deliver sufficient specified levels of micronutrients to food aid recipients in developing nations.

**Shipping and Storage:** There was little loss of vitamins and minerals found in the dry commodities during shipping and storage. The conclusion from these results is that vitamin loss in the dry commodities is statistically significant, but it is not a serious overall problem. The one-third loss of vitamin A found in WSB nine months after production was the largest loss observed, but this level of loss is within the expected vitamin A loss endured by the US food industry. WSB makes up a relatively small proportion of processed food aid, and manufacturers could probably remedy the problem through a change in the fortificant used. There was little loss of vitamin A in wheat flour or bulgur or of vitamin C in CSB and WSB. There is no need to change the packaging, lower the moisture content or implement any of the related actions that have been proposed. Any such action would likely be expensive and ineffective. The one action recommended is that the mills and premix manufacturers make sure the vitamin A they use is of good quality and meets the stability standards specified by the USDA.

**Consumer Level Losses:** The MAP also identified losses at the consumer end. **Cooking processes used routinely with CSB and WSB by Title II recipients overseas can cause large losses of vitamins A and C.** When blended, fortified Title II cereals were used to make a simple gruel at delivery sites, using a common preparation method for feeding children, the vitamin A retention was only 50% of post-shipment levels. Better vitamin retention (70%) was found in foods with lower moisture content, such as dumplings and ugali, a paste made out of corn meal and CSB that is commonly prepared in Africa. Cooking losses were not altogether unexpected in these fortified, blended cereals, since the labile nature of these vitamins leaves them vulnerable to losses in certain cooking processes.

**Overall Losses Estimate:** Taking this cooking loss, combined with low initial levels supplied by some of the products and vitamin A losses during storage of WSB, **the amount of vitamins A and C actually delivered to the recipients was well below expectations.** In some extreme cases, only trace levels of these two vitamins were found in the cooked food.

## Accomplishments

Throughout its course, this project demonstrated to the producers, USDA and PVOs the importance USAID attaches to micronutrient delivery in food aid commodities. A primary recommendation was the need for the USDA to better monitor and enforce micronutrient fortification of Title II, P.L. 480 food commodities, recognizing the importance now attached to delivering needed vitamins and minerals to the recipients of this program.



Furthermore, it became clear that the economic losses to the government could be significant. In one extreme example, the government was paying nearly six dollars to fortify every metric ton of bulgur wheat with vitamin A, while the product contained less than two dollars worth. The cost of quality control would have been a fraction of these losses.

As a result of the MAP findings, USDA is working with USAID to establish standards for analytical micronutrient “indicators” that will be used to determine whether the different commodities have been properly fortified, a program of regular testing of each lot of fortified commodity, and an enforcement program to ensure that the producers are meeting fortification standards.

USDA has also begun investigating the adoption of a Total Quality Systems Audit (TQSA) program that focuses on the manufacturing process and operating procedures. It is an alternative to end-item inspections and verifies that a supplier has the capability to produce food products which consistently meet USDA standards, to deliver on time, and to respond to and resolve consumer complaints.<sup>1</sup> TQSA evaluates capability and performance of these factors. Programs similar to TQSA have become one of the main tools used by the U.S. food industry to ensure continued quality. USDA is implementing TQSA over the next five years for all vendors who sell food products to the Farm Service Agency (FSA). SUSTAIN endorses the current efforts by USDA to establish a TQSA program for P.L. 480 commodities, and recommends that fortification practices be included as a component.

The visits of the SUSTAIN MAP team to the U.S. production sites caused producers to become more aware of the fortification component of their operation. It has already led one producer to make the effort to improve the uniformity and quality of its fortification practices, resulting in the development of a new fortification premix, modified operating procedures and improved quality control testing. Other plants have been made aware of problems in fortifying their products, but it is not known to what extent corrective action has been taken.

Some of the problems found with low vitamin A levels at production and loss of vitamin A in the dry commodity resulted from some companies ignoring existing USDA specifications on the type of vitamin A to be used in these commodities. SUSTAIN recommends that USAID work with USDA to enforce these specifications and encourage producers and vitamin suppliers to seek ways to improve vitamin A stability. Continued exploration of new forms of vitamin C that can provide improved stability during food preparation is also recommended. Attention should be turned to identifying and promoting cooking methods that maximize vitamins and recommendations should be made to PVOs and other organizations receiving fortified P.L. 480 foods on such cooking techniques.

The expert panel advising SUSTAIN on the MAP activity has concluded that the recommended minimum micronutrient standards in combination with a TQSA program is the only practical and achievable way to ensure adequate levels and uniformity of micronutrients in fortified Title II P.L. 480 food commodities. USAID and USDA are already working toward these goals through the establishment of a SUSTAIN-administered International Food Aid Commodity Secretariat. This forum provides the opportunity for private and public stakeholders to conduct dialogue regarding food aid micronutrient quality assurance and delivery.

While this report identifies some serious problems in delivering vitamin A through fortified, cereal-based foods, it recommends that vitamin A fortification of these foods continue owing to the recognized importance of delivering vitamin A to food aid recipients. As an additional means of supplying vitamin A to the target population, the MAP team prepared a report on the feasibility of adding vitamin A to vegetable oil for use in Title II programs. The report recommended, and USAID and USDA initiated, the fortification of refined vegetable oil as of December 1, 1998.

## Recommendations

The results of this study have led to the following specific recommendations for USAID, USDA and their partners to improve the implementation of the food aid program:

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<sup>1</sup> See: USDA, Farm Service Agency, Commodity Operations website <http://www.fas.usda.gov/daco/trends/TQSA.htm>. Vendors will have to develop and implement quality management systems (QMS), based on International Organization of Standards (ISO 9000) quality standards, which states how they will produce and deliver their food products. A trained USDA audit team will review QMS and its implementation to ensure consistently safe, high quality products. Vendors will be rated and qualified to bid only if they meet the standards.

- Monitor and enforce minimum micronutrient specifications currently applicable to processed fortified P.L. 480 cereals at U.S. food aid processing plants.
- Establish, monitor and enforce a minimum, end-product vitamin standard for one vitamin and one mineral in fortified blended foods (CSB and WSB) at U.S. food aid processing plants.
- Establish vitamin A as the micronutrient indicator for all P.L. 480 processed fortified cereals. In processed fortified and blended foods (such as CSB and WSB), establish vitamin A as the vitamin indicator and iron as the mineral indicator.
- Remove all maximum standards on micronutrients or enforce minimum standards only in P.L. 480 processed cereals.
- Bulgur and wheat flour producers, especially, need to work with fortification premix producers to correct the problem with low vitamin A levels found in their commodities.
- Incorporate micronutrient fortification in the Total Quality Systems Audit (TQSA) at U.S. food aid processing plants.
- Consider allowing combined addition of vitamins and minerals to CSB and WSB.
- USAID and USDA should help facilitate technical assistance to manufacturers of fortified P.L. 480 commodity producers on how to improve compliance and uniformity of micronutrient addition.
- Enforce the current stability specifications on the vitamin A required in fortified P.L. 480 commodities.
- Encourage mills and premix suppliers to improve vitamin A stability.
- Continue fortifying processed and blended foods with vitamin A.
- Investigate use of the more heat stable forms of vitamin C in CSB and WSB.
- Investigate precooked foods as an alternative means to deliver vitamin A and C to food aid recipients.
- Include information on vitamin retention in the Commodity Reference Guide for use by field partners who provide food aid.

## I. INTRODUCTION AND BACKGROUND

The U.S. provides much of its global food assistance under the Agricultural Trade Development and Assistance Act of 1954, also known as Public Law 480 (P.L. 480). Since its enactment, the United States Government has distributed some 375 million metric tons of food valued at over 50 billion dollars, working through many partners in the U.S. and abroad, including non-governmental and private voluntary organizations (NGOs and PVOs), agricultural producer groups, and the World Food Program (WFP). The U.S. Government (USG) continues to be the largest food assistance donor worldwide. Through P.L. 480 food assistance program (Titles I, II and III), the United States has provided 1.1 billion dollars worth of food assistance in fiscal year 1998, using 2.84 million metric tons of commodities, including value-added fortified processed and blended Title II foods which are the focus of this study. Under the Title II program, the U.S. Agency for International Development (USAID) through its field partners and country Missions, identifies food aid needs and the Office of Food for Peace in Washington authorizes the U.S. Department of Agriculture (USDA) to competitively procure food commodities from U.S. private food processors.

In the 45 years since its inception, USDA and USAID have improved the quality and safety of the food commodities shipped to needy people under P.L. 480 and other food aid legislation. Specifically, micronutrient fortification of P.L. 480 food commodities, which began in 1966, has enhanced the potential to address nutritional deficiencies in developing countries and emergency relief situations by providing additional vitamins and minerals through a wide variety of processed foods. In fiscal year 1997, this amounted to six micronutrient fortified cereals and two specially blended and fortified cereals, totaling 590 metric tons (MT) that reached over 20 million people (see Table 1). The value in fortifying these products has grown in importance in recent years with the discovery of the critical role micronutrients play in the human diet, not only in preventing deficiencies under conditions of scarcity and poverty, but also in enhancing health and well-being more generally.

**Table 1. P.L. 480 Title II Fortified Cereal Foods**

<b>Commodity</b>	<b>Quantity Provided During FY 1997 (1,000 Metric Tons)</b>	<b>Average Cost<sup>2</sup> (\$/MT)</b>	<b>Value (Million \$)</b>
<b><u>Fortified Processed Cereals:</u></b>			
Wheat Flour	161	305	49.1
Bulgur	68	258	17.5
Bulgur, Soy Fortified	60	276	16.6
Corn Meal, Soy Fortified	43	310	13.3
Corn Meal	24	311	7.5
Sorghum Grits, Soy Fortified	14	304	4.3
<b><u>Fortified Blended Cereals:</u></b>			
Corn Soy Blend (CSB)	211	335	70.7
Wheat Soy Blend (WSB)	9	458	4.1
<b>Totals</b>	<b>590</b>		<b>183.1</b>

Changes in the fortification standards for the fortified P.L.480 commodities have occurred simultaneously with increased knowledge in the nutrition and food processing sciences. These changes include the following:

- 1982 increase in iron and B vitamin levels in fortified wheat flour;
- 1988 doubling of vitamin A levels in all fortified cereal based foods;
- 1997 inclusion of folic acid in fortified processed cereals;
- 1998 magnesium added and zinc levels increased in CSB and WSB, while the level of B<sub>12</sub> decreased;
- 1998 vitamin A added to refined P.L. 480 vegetable oil.

The most recent changes were based, in part, on recommendations from a USAID-commissioned 1994 technical review paper (1) and field studies by SUSTAIN (8). Some of the recommendations have not been implemented,

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<sup>2</sup> Average delivered cost including freight.

such as switching to more absorbable forms of iron, while others led to changes not being made, such as the increase in vitamin C levels (see Appendix A).

In 1996 Congress directed USAID to initiate a pilot program to increase the vitamin C content of CSB and WSB to 90 mg/100 g and report on the results. A pilot study conducted by SUSTAIN provided the basis for the recommendation by the National Academy of Sciences accepted by USAID to retain the level of 40 mg/100 g of vitamin C in these blended foods.

In the course of investigating these proposed changes, USAID developed an overall concern with the uniformity and stability of vitamins and minerals added to all fortified and blended P.L. 480 food commodities. Laboratory studies done for USAID with the assistance of the U.S. Army food research laboratory at Natick, Massachusetts and by the FDA in 1992 suggested possible problems with the stability of added vitamin C, but they were not able to quantify how much would be lost under field conditions. A 1994 field test in India (2) showed high variability in vitamin A levels in CSB, with some products containing far less than the target levels. This suggested problems with fortification at the plants and/or significant losses during shipping and storage. The OMNI project study in 1994 (1) recommended establishing a quality control program for ensuring micronutrient content of P.L. 480 foods prior to shipment. Based on SUSTAIN's vitamin C pilot study, in 1997 the National Academy of Sciences recommended that better assurances of product quality should be given before changing nutrient profiles of food aid (10). (Detailed discussion of these studies are presented in Appendix A.)

One aspect of this concern has been the specification and enforcement of standards for micronutrient enrichment and fortification by USDA. All processed food provided under Title II programs, with the exception of rice, is required to meet the U.S. standards for enriched cereals, meaning that they must be fortified with B vitamins (thiamin, riboflavin, folic acid and niacin) and iron. USDA policy requires that any changes made in the U.S. enrichment standards for foods with a U.S. Standard of Identity automatically be applied to the same foods used in the Title II Food for Peace program. Originally, enrichment was intended to replace nutrients lost in refining. The levels of micronutrients added by manufacturers now make up for the difference between the minimum enrichment standard and the amount of the nutrient remaining in the refined cereal, plus a reasonable overage to ensure that the standard will be met. In addition to meeting the appropriate U.S. domestic enrichment standard, all Title II processed foods are required to be fortified with vitamin A because of the great need for this vitamin by most populations targeted for food aid.

**Table 2. Micronutrient Standards<sup>3</sup> for Fortified P.L. 480 Processed Cereals**

<b>Commodity</b>	<b>Thiamin mg/100g</b>	<b>Ribo- flavin mg/100g</b>	<b>Folic Acid mg/100g</b>	<b>Niacin mg/100g</b>	<b>Vitamin A IU/100g</b>	<b>Iron mg/100g</b>	<b>Calcium mg/100g</b>
Wheat Flour and Soy Fortified Flour	0.64	0.40	0.15	5.29	2205-2644	4.41	110
Corn Meal, Soy Fortified Corn Meal, and Corn Masa Flour	0.44 - 0.66	0.26 - 0.40	0.15 - 0.22	3.53 - 5.29	2205-2644	2.86 - 5.73	110 - 138
Bulgur and Soy Fortified Bulgur	0.44 - 0.66	0.26 - 0.40	0.15 - 0.22	3.53 - 5.29	2205-2644	2.86 - 5.73	110 - 138

Therefore, micronutrient standards for fortified processed foods, shown in Table 2, are the same as those used under U.S. Food and Drug regulations for these foods, with the additional requirement of vitamin A and calcium. They are given as a minimum with overages left to good manufacturing practices for wheat flour or as a minimum-maximum

<sup>3</sup> Single values indicate a minimum with overages left to good manufacturing practices. Two values separated by a dash (-) indicate a minimum - maximum allowable range.

range with the others, the same as required under FDA standards for enriched cereal foods. Vitamin A, however, is always given as a range. There is no FDA standard for enriched bulgur wheat, so the standards for bulgur were based on those existing for wheat flour at the time bulgur was developed as a P.L. 480 commodity many years ago. The standards for wheat flour were subsequently increased to the higher values, but bulgur remained at the old levels. These micronutrient standards for fortified processed foods are operative for all processors. However, because the commodities are not tested for micronutrients, there has been no real monitoring or enforcement of these specifications or standards.

The micronutrient fortification for the two blended foods (CSB and WSB) is shown in Table 3. USDA regulations specify the composition of the vitamin and mineral premixes to fortify CSB and WSB, which are the same for both commodities. In contrast to the processed fortified cereals, the values shown in Table 3 for the blended foods are *target levels* added and not necessarily the *final levels* in the product, although many groups have used them, incorrectly, in that manner. USDA applies no final product (end-product) specifications for blended commodities and there is currently no testing of the commodities for final micronutrient content to ensure that they have been properly fortified.

**Table 3. Micronutrient Addition Target Levels in Fortified Blended Foods**

<b>Micronutrient</b>	<b>units per 100g</b>	<b>CSB/WSB Target Levels, prior to January 1998</b>	<b>CSB/WSB Target Levels, after January 1998</b>
Calcium	mg	775	775
Calcium d Pantothenate	mg	2.76	2.76
Folic acid	mg	0.20	0.20
Iodine	ug	45	57
Iron	mg	14.7	14.7
Magnesium	mg	0	82.5
Niacin	mg	4.96	4.96
Pyridoxine HCl	mg	0.17	0.17
Riboflavin	mg	0.39	0.39
Salt	g	0.65	0.81
Thiamin	mg	0.28	0.28
Vitamin A	IU	2,315	2,315
Vitamin B12	ug	3.97	1.32
Vitamin C	mg	40.1	40.1
Vitamin D	IU	198	198
Vitamin E	IU	7.5	7.5
Zinc	mg	0.91	3.98

To assist USAID in resolving these concerns, on September 30, 1995, USAID's Bureau for Humanitarian Response (BHR) set up Cooperative Agreement No. FAO-0800-A-00-5033-000 with the National Cooperative Business Association (NCBA) for SUSTAIN to establish the Micronutrient Assessment Project (MAP) to research the stability and availability of micronutrients in Title II food aid commodities (Appendix B). SUSTAIN had been identified by the Global Bureau as an organization with access to the wide technical expertise available through its network of U.S. food technologists and other food and nutrition experts, which could assist USAID with assessing, enhancing and establishing quality assurance procedures in the fortification and enrichment of P.L. 480 commodities.

To help follow up on these recommendations and to coordinate a variety of technical resources dealing with micronutrients in P.L. 480 commodities, the USAID Office of Food for Peace requested that SUSTAIN establish the International Food Aid Commodity Secretariat (IFACS). This mechanism was established in May 1997 to facilitate the exchange of information among all P.L. 480 stakeholders.

This ***Final Report on the Micronutrient Assessment Project*** provides a full accounting of the background, methods, accomplishments, analysis and recommendations derived from the MAP activities over the course of its Cooperative Agreement. The remainder of this report is divided into the following sections:

- A description of the **MAP Goal and Objectives**: Section II
- **Procedures and Methods** used throughout the MAP data collection and analysis: Section III
- **Findings and Conclusions** regarding micronutrient levels, uniformity and stability: Section IV
- **Recommendations & Implications**: Section V
- A review of MAP and other related SUSTAIN **Accomplishments**: Section VI
- **Appendices** which provide relevant subject reviews, a list of advisors, scope of work, and details of the data analysis.

## II. THE MICRONUTRIENT ASSESSMENT PROJECT (MAP)

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### A. Program Goal and Objectives

The overall goal of the MAP was to contribute to the alleviation of nutritional deficiencies in the developing world. The specific purpose was to contribute to USAID/BHR's knowledge of the stability and availability<sup>4</sup> of micronutrient fortificants in food aid commodities and to make recommendations designed to improve the long-term effectiveness of that program on the target populations.

To accomplish the purpose, activities were designed with the following project objectives (as stated in Cooperative Agreement No. FAO-0800-A-00-5033-00, 28 September 1995):

1. To contribute to an increased understanding of the stability and loss of the micronutrients added to food aid commodities.
2. To assess the stability of selected micronutrients added to specific Title II commodities, from the point at which the micronutrients are initially added to the commodities up to the point of consumption in the field.
3. To identify specific conditions that result in the loss or deterioration of micronutrient fortificants.
4. To identify particular problem areas in the handling and storage of fortified food aid commodities that are detrimental to the stability of added micronutrients.
5. To make recommendations for improving the stability and nutritional availability of specific fortificants.
6. To identify particular problem areas in the processing of fortified food aid commodities that affect the availability of micronutrients in the finished commodity at plant sites, and to make recommendations on improvement of this processing.

The MAP Cooperative Agreement originally contained the first five research questions related to the stability of specific micronutrients (i.e., what amount is retained) in food aid commodities up to the time they reach the consumer. A sixth objective was added on the basis of preliminary tests because it was clear that the amount of nutrient reaching the consumer is not only a matter of stability, but also a matter of the commodity leaving the manufacturing plant with the correct level of fortificant present throughout the entire shipment<sup>5</sup>. A primary task of MAP was to make recommendations on food aid commodities at the end but also throughout the course of the study.

### B. Study Design

The study was designed to provide answers to the following questions related to fortified Title II, P.L. 480 food commodities:

1. What are the levels of added micronutrients found in specific food aid commodities at the point of production in the U.S and how close do they come to meeting current standards or targets? This is the amount of the added vitamin or mineral actually found in the processed food at the plant.

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<sup>4</sup> "Availability" in this context means the amount of micronutrients provided by the food and not the bioavailability, or how much of the added micronutrients are absorbed by the body.

<sup>5</sup> Tests run in connection with the Vitamin C Pilot activity indicated serious problems with the levels and uniformity of that added micronutrient at the manufacturing plant. Some of the companies and specific plants were also involved in the fortification of food aid commodities with other vitamins and minerals. With the approval of the USAID/BHR and the Farm Service Administration (FSA) of the USDA, the MAP team arranged for subsequent tests from samples taken at production sites. These tests revealed low levels of vitamin A in bulgur and wheat flour and led to the additional testing of vitamin A in official Government (FGIS) samples taken of those two commodities.



2. What is the uniformity of the selected micronutrients found in specific food aid commodities at the production plants and previous to shipping? This is the amount of variation in the vitamin or mineral within bags, between bags and between lots.
3. What is the stability (degree of retention) of these micronutrients following shipping and storage of the food? This degree of retention is the proportion of the vitamins retained in the dry commodity from the point it leaves the production plant and the point just prior to cooking (or other food preparation) by consumers.
4. What is the stability of vitamins during normal food preparation methods? This degree of retention is the proportion of the vitamins retained in the food commodity from the point just prior to food preparation by a consumer to the point when the cooked commodity is about to be consumed.

### **Fortified Food Commodities Selected for Study**

This study investigated the most frequently used food aid commodities. The annual use of the different fortified P.L. 480 commodities, provided in Table 1 for FY97, shows that CSB has the highest volume (211 MT) followed closely by wheat flour (161 MT). Next are soy fortified and regular bulgur (128 MT) and then corn meal (67 MT). The MAP selected these four most widely used fortified cereal-based foods and WSB. WSB, along with CSB, is used primarily as a complementary food and therefore is a potential source of micronutrients to the highly vulnerable weaning-age child group. Because of the importance of CSB, both in terms of volume and as a means of supplying micronutrients, CSB became the principal subject of the study.

While wheat flour, corn meal and bulgur products are fortified with certain micronutrients, CSB and WSB are the only two foods in the food aid commodity mix that are “blended”, meaning in this case that they are fortified with protein, fat and a full spectrum of vitamins and minerals. Only CSB and WSB have added vitamin C. WSB was studied in detail in the Vitamin C Pilot Study because it had vitamin C added, and so it was included in the MAP, even though it is produced in small amounts (9 MT) compared to the other commodities. It was also instructive to include WSB because it is alone is fortified using a batch process, as opposed to the continuous process used with all the other food aid commodities.

### **Micronutrients Investigated**

Out of the many micronutrients added to food aid, the MAP selected vitamins A and C because of their high cost, nutritional importance and poor stability relative to the other micronutrients. Iron and niacin levels were selected because their high level of stability provides an additional basis for judging uniformity of the applied vitamin and mineral premixes. (See Appendix I, Tables 3-5 for the nutritional profile and added nutrients to Title II food aid.).

Standard analytical procedures run by an established commercial lab were used throughout the study in order to assure consistency in the analytical methodology. Using only one laboratory minimized potential inter-laboratory variations. Following standard protocols provided measurements that could be compared to those of other studies using the same procedures.

### **Rationale for Production Sites Selection**

Plants and production contracts for processed and blended food aid were chosen to illuminate the range of processing done. These intensive site studies were supplemented with samples provided by USDA from other plants and production runs. Because of the wide variability found at the first production site sampled, it was determined all eight plants producing blended foods (CSB and WSB) were selected for study, along with one production plant each for wheat flour, bulgur and corn meal. Along with the USDA samples, it was thought a good representation of the production of fortified food aid products could be obtained.

### **Rationale for Country and Consumer Site Selection**

The MAP protocol called for product sampling in four different countries, including at least one refugee (emergency) feeding situation and one development situation. Consumer sites were selected to represent Title II development and relief activities under a variety of conditions, including wide differences in climates, length of time it took commodities to reach the recipients, cooperating sponsor groups, and types of food aid programs. Sampling trips were made to five countries on three continents. India was chosen since it is the largest Title II program

worldwide, receiving 214,900 metric tons worth over \$93.7 million for distribution to almost 7.5 million people in development activities in 1997. Peru, Bolivia and Haiti together represent the bulk of Title II assistance in Latin America and the Caribbean (LAC). These programs distributed a total of 168,510 metric tons valued at \$87 million to 2.1 million people. Tanzania was representative of the refugee situation in Africa.

### III. PROCEDURES AND METHODS

The procedures and methods required to cover the full range of micronutrient concerns were a complex combination of sampling and analytic testing that began in the U.S. processing plant and ended with cooked food in a recipient's kitchen or refugee site. In all, 150 lots of the five food aid commodities were selected for investigation and numerous analytical tests were done on the four focal micronutrients at various points along the production to consumption chain (Table 4). In addition to the testing for levels, uniformity, and stability of micronutrients, special studies were done to test the composition of the premixes, their stability in over a period in cold storage, and the food preparation under simulated conditions. MAP employed standard state-of-the-art methods for laboratory assays of nutrients and for statistical analysis.

**Table 4. Summary of Sub-Studies Performed on Fortified Foods (MAP and FGIS sampling)**

Nutrient	Levels (processing plants )		Uniformity (processing plants)		Stability, dry (country sites)		Stability, cooked (lab. & country sites)	
	Food*	Number	Food	Number	Food	Number	Food	Number
Vitamin A	CSB	5	CSB	4	CSB	2	CSB	3
	Cornmeal	1	Cornmeal	1				
	WSB	1	WSB	1	WSB	1	WSB	3
	WF	9	WF	1	WF	2		
	BW	3	BW	1	BW	2		
Vitamin C	CSB	5	CSB	5	CSB	1	CSB	3
	WSB	1	WSB	1	WSB	1	WSB	3
Iron	CSB	3	CSB	3	CSB	1		
	Cornmeal	1	Cornmeal	1	WSB	1		
	WF	1	WF	1				
	BW	1	BW	1				
Niacin	CSB	3	CSB	3			CSB	1
	WSB	1	WSB	1			WSB	1

\* WF is wheat flour and BW is bulgur wheat.

#### A. Determination of Levels and Uniformity at the Production Plant

##### Studies of Production

Production studies involved testing two types of commodity samples to determine how well the plants are fortifying P.L. 480 commodities. The first were direct samples taken during production runs by MAP scientists at plant sites over a two to three day period, representing only a few lots, except in the case of wheat flour where the samples were taken over a three week period (Table 5). The other type of samples was composite lot samples taken by FGIS at the plants and sent to an analytical laboratory identified by MAP.

**Table 5. Summary of Production Plants Directly Sampled**

Plant <sup>6</sup>	Product	Date sampled	Type of production
A	CSB	June '96	Continuous
B	WSB	July '96	Batch
C	CSB and Corn Meal	Oct. '96	Continuous
D	CSB	Jan. '97	Continuous
E	CSB	Apr. '97	Continuous
F	Wheat Flour	July '97	Continuous
G	Soy Fortified Bulgur	Aug. '97	Continuous
H	CSB	Aug. '97	Continuous

### Method of Direct Product Sampling

Direct samples taken during a production run showed how micronutrient levels varied from hour to hour and from bag to bag. They represented conditions during a short slice in time in the production history of a particular plant. Due to concerns about the uniformity of the micronutrients added to CSB, it was decided to directly sample as many CSB plants as possible in this way. As it turned out, five of the six plants producing CSB were sampled. One plant producing each of the following products was sampled: WSB, wheat flour, corn meal and bulgur. These four represented basic differences in P.L. 480 commodities in terms of composition and particle size. In all approximately 36 production lots, averaging 125 MT each, were sampled.

Based on the recommendations of the MAP Statistical Advisory subgroup (see Appendix H) the study design called for collection of 48 samples distributed evenly over a 2 to 3 day production run. This was generally, but not always, achieved. In some cases, fewer than 48 samples were collected; in other cases, sampling took place over a longer period than three days. Ten of the samples were duplicated for use as blind analytical checks. All samples taken at the mill were sent to the laboratory within three days of sampling. Plants were instructed not to alter or slow down the production of the commodities in any way that would make them different from a normal production run. Arrangements were made through USDA and Protein Grain Product International to sample the production runs according to the following procedures:

1. The company to be sampled and the responsible FGIS field office were contacted to confirm arrangements on sampling procedures, times, and materials.
2. A SUSTAIN representative visited the production site to review the sampling procedure with plant and FGIS employees.
3. With assistance from FGIS inspectors and plant quality control (QC) staff, SUSTAIN collected samples by one of two procedures: (1) removing a filled bag from the line, scooping a sample from the top of the bag, and putting the sample into an eight ounce black plastic container with a tight snap-on lid; (2) scooping the sample from the top of the bag directly into the eight ounce plastic container just after the bag was filled. Each container was labeled with the date and time which constituted the sample number. Bag numbers and packing machine lines were also recorded when appropriate.
4. Duplicate samples were taken by removing bags from the line, mixing the top portion of the product with a scoop, and filling two sample cups. The duplicates were given different sample numbers and dummy times so that they could not be identified as such by the analytical laboratory.
5. In the case of one production run of CSB (plant A) and WSB (plant B), the sampled bags were labeled with the sample information, given a distinctive colored mark on the sides and bottom, and returned to the production line.

<sup>6</sup> Throughout this report production plants are identified only by a letter in order to maintain the confidentiality of the companies involved. Each letter indicates a production facility for a particular commodity. In some cases two of the sampled commodities were manufactured at the same location. Plant C produced both corn meal and CSB on the same equipment. All of the plants are located in the Midwest United States. A detailed description, with diagrams of the plants and their production processes, are provided in Appendix E.

6. Samples of the vitamin premix were taken each day from the premix feeder.
7. With help from plant personnel, SUSTAIN diagrammed the production method used and recorded the following information:
  - Times of personnel shift changes
  - Manufacturer and lot numbers of vitamin and mineral mixes used
  - Hourly production rates (bags/hour)
  - Daily temperature and weather conditions
  - Any special circumstances or events (e.g., chokes, accidents)

The samples from the production runs were sent by overnight package delivery to Lancaster Laboratories in Lancaster, Pennsylvania, for immediate testing of vitamin C (ascorbic acid) followed by testing of vitamin A, iron and any additional tests.

**Vitamin Premix Samples:** Samples of the vitamin premix used each day during production were taken directly from the vitamin feeder. They were tested for vitamin C, vitamin A and niacin by the quality control laboratories at two premix manufacturers (Watson Foods and American Ingredients) that routinely do this type of assay using high-pressure liquid chromatography (HPLC). The samples were identified only with a number, so the laboratory did not know whose products they were testing.

**Within-Bag Variability:** Within-bag variation at the production site was determined by collecting samples from soy-fortified bulgur samples at plant G. A single sample of approximately 100g was extracted from three different positions of the bag: the top third of the bag (position “a”), the middle third (position “b”), and the bottom third (position “c”). Each sample was analyzed separately.

Within-bag variation after shipping and storage was determined by collecting samples from 13 bags of CSB in Tanzania and 9 bags of WSB in Haiti. Single samples of approximately 100g each were extracted from the three different bag positions (described above) and each sample was analyzed separately. In addition, 21 bags of bulgur from one lot were sampled from one of the three bag locations.

**Special Bulgur Tests:** The MAP study had an immediate effect on improving the uniformity and long-term quality assurance at a bulgur production facility where the personnel were very concerned about the low level of vitamin A in samples tested at their plant. Because of this company’s dedication to producing a quality product, they made special efforts to improve the process so that the vitamin A levels would be within specifications. These included the following measures:

1. Conducting vitamin A analytical tests on all lots of bulgur and soy-fortified bulgur produced in the plant until the problem was solved. Some of these results were made available and are shown in Appendix D;
2. Increasing the addition rate of the premix to ensure adequate levels of vitamin A fortification. This was a temporary measure because it also increased the levels of the other micronutrients being added and was more costly to the producer and hence less cost-effective for the P.L. 480 program;
3. Eliminating the suction from the packing line in case the vitamin A, which is fairly light, was being pulled out of the product. This resulted in a more dusty packing area and packing line personnel having to wear dust masks;
4. Asking the premix supplier to come up with a better premix. This resulted in a special bulgur fortification premix utilizing a special, non-dusting carrier.

## **Composite FGIS Lot Samples**

In addition to direct sampling, MAP was provided composite lot samples by the FGIS for study. These samples are routinely taken throughout the production of a lot. The samples are then combined to represent the entire lot. These samples are used by FGIS to routinely test for moisture, protein and other properties of food aid commodities. FGIS composite lot samples are the official samples used by the USDA to determine whether a lot meets specifications for these and other properties of the food. In this way, it was possible to analytically test over 200 additional lots of food aid.

The micronutrient assay on these samples is comparable to the mean result for each lot from the direct method. These assays give a good indication of how closely the plant met the specification or target for that lot, but provided no information on the variability within that lot. The assays tell us the variability between lots, which is not provided in the first type of sample testing, and gives a much better picture of how well a plant is doing in meeting current or proposed fortification standards since they represent a much larger quantity of product produced over a longer time interval. Even these samples are limited since they are only of wheat flour and bulgur taken over two periods of a couple months each. Regular testing of these composite samples is one option to better control fortification practices.

The FGIS laboratory takes one to two weeks to complete the analyses of the lot samples received from production plants. The FGIS lab was instructed to collect all samples of wheat flour and bulgur from January 1998 through September 1998 and send them to Lancaster Laboratories for analysis. The FGIS lab collected about a month's worth of samples and held them in frozen storage before sending them out. In some cases the FGIS lab used most or the entire sample for their own analyses, so none was left for additional testing. Also, there were a number of samples received between March and June that were inadvertently discarded. On receipt of the sample, the Lancaster lab personnel recorded the information, conducted an analysis of vitamin A content and kept any remaining samples at -20° C. The time between production and vitamin A testing was between one to two months.

## **B. Determination of Stability of Vitamins During Shipping and Storage**

### **Method for Determining Stability**

The stability of the added vitamins was assessed by the following methods:

#### **1. Comparison of Mean Levels**

This method compares the mean and the variation of the vitamin content in the products at production to the mean and the variation of the micronutrient content in the same lot of product just prior to being used in food preparation in the recipient country. The Student's T test and confidence interval were used to determine whether the means were statistically different from each other.

#### **2. Comparison of Paired Samples in Specially Marked Bags**

Once the specially marked, sampled bags were located in the field and sampled, the vitamin content was compared to the vitamin content found in those same bags during production. The Student's T test for paired samples and confidence intervals were employed to determine whether the paired values were statistically different. This method could only be used on the WSB production since insufficient marked CSB bags were located in the field.

#### **3. Comparison of Lot Means at Recipient Sites to FGIS Composite Samples for that Lot**

This method compares the value of the vitamin content in the official FGIS composite samples taken at production to the mean of the vitamin content in the same lot of product taken at the recipient site. The Student's T test and confidence intervals were used to determine whether the levels were statistically different from each other.

## Recipient Country Sites Sampled

Sampling trips were made to Haiti, Tanzania, India and Peru. A local SUSTAIN representative sampled product in Bolivia. The trips were arranged to collect samples from specific contract numbers, i.e. those which identified the production runs of interest to the MAP study. Once the MAP team had obtained confirmation from the cooperating sponsor in the recipient country that bags with the contract number of interest had arrived at the final distribution sites and were available for sampling, sampling trips were scheduled. No attempt was made to alter or expedite the normal distribution of the commodity.

## Sampling Procedures

In each of the five countries dry commodity samples were collected by laying the bag flat on the ground and cutting the bag at the top, or middle, or bottom with a razor blade. A single sample of about 100g was extracted from the bag, and in most cases the position of the cut in the bag was noted. The sample was put into sampling cups with either screw-top lids or snap-seal lids. In Peru and Bolivia, however, the samples were placed in polyethylene twirl-packs, folded shut, tightly secured, and placed in a black plastic bag to protect the samples from vitamin A degrading light. SUSTAIN brought the samples back to the United States for analysis within two weeks of collection. In the case of Bolivia, the samples were sent back by overnight courier service. The sampling containers remained stored at ambient temperatures in sealed plastic bags and placed in opaque cardboard boxes until delivered to the laboratory.

**Table 6. Recipient Sampling Sites**

Country Site	Type/ Program	Product	Producer	Production Date	Recipient Site Sample Date	Time Interval Between Sampling (in months)
Tanzania	Refugee	CSB	Plant A	Jun 96	Jan 97	7
Haiti	Development	WSB	Plant B	Jul 96	Mar 97	9
India	Development	CSB	Plant C	Oct 96	Mar 97	5
Peru	Various	} Wheat Flour	Various	Jul 98	Sep 98	2
Bolivia	Monitization		Various	Feb 98	Oct 98	9
Peru	Various	} Bulgur	Plants G,L	Jul 98	Sep 98	2
Bolivia	Various		Plant L	Feb 98	Oct 98	9

**Haiti:** WSB produced by Plant B in early July was unloaded in the ADRA warehouse in Port au Prince, Haiti in mid-October 1996 and transported to the food distribution centers. For each batch, 68 bags were sampled at production and specially labeled. To allow SUSTAIN to track down the specially marked bags, ADRA was asked to deliver five of the specially labeled bags to ten pre-selected feeding centers during their normal three-month distribution cycle.

The selection of the feeding centers was based on the type of food distribution program and their location (urban versus rural). There were three types of feeding programs run by ADRA, but WSB was distributed through only two of them: the Maternal Child Health (MCH) and Other Child Feeding (OCF) programs. The locations selected were: 1) a primary MCH and a primary OCF in an urban area, and 2) two primary MCH centers and one primary OCF center in a rural area. In addition to these five locations, secondary centers in close proximity to the primary centers were selected to ensure there was a matching pair of centers in each of the five distribution areas.



Distribution to the selected centers began in late January 1996, and the sampling took place in the centers in March 1997. Typically, a center receives three months' worth of commodities at a time and the commodities are distributed to the recipients twice a month. The commodities are consumed during the two to three weeks between distributions.

**Tanzania:** CSB produced in Plant A between June 24 to 28, 1996, was sent to the refugee camps in western Tanzania and was distributed in December 1996. Logistics and internal transport of food commodities were handled by the World Food Programme and distribution was under the management of UNHCR. The focus in Tanzania was on observing food preparation practices and sampling CSB just prior to and after cooking. No attempt was made to determine vitamin retention in the dry CSB of this lot because of the wide variation in vitamin levels found at production.

**India:** CSB production was sampled at Plant C in early October 1996 and met the criteria of being in control. Four lots (136 MT/lot) of this procurement were distributed in the Cochin region in Southern India. Most of the bags sampled came from two lots only. Sampling was done at six different schools and at two different warehouses serving the area. The warehouses were privately run under contract to WFP. The bags found in the schools were kept in school pantries. The schools, which each teach from 12 to 40 children, received CSB several times a month. The CSB was provided to the schools for their school lunch program and it was served once a day.

**Peru:** Peru was chosen as the site to collect wheat flour and bulgur samples because of the large quantities of these two commodities sent there. The sampling trip to Peru was made September 1998. During that trip SUSTAIN first made contact with the PVOs receiving P.L. 480 commodities (PRISMA, CARE, ADRA and CARITAS) in order to explain the purpose of the MAP study and of trip sampling objectives.

Suitable contracts were located in three Peru warehouses. The bags of commodities were stacked in large piles, often 20 feet high, making it practical to sample only the top bags no more than three bags deep. In Peru very few of the bags had readable lot numbers. Either lot numbers were not printed on the bag or they had rubbed off during handling. First bags with the proper contract number and the same lot number were found and brought down to the floor of the warehouse. These were collected randomly around the warehouse when available, but in some cases the bags with the same lot number were all on the same pile or pallet. When no lot number could be found for a target contract, bags of that contract number were collected randomly from around the warehouse.

**Bolivia:** Bolivia was selected as the second South American country since it receives large amounts of wheat flour for monetization as part of its P.L. 480 Title II program while little wheat flour from the specific FGIS-sampled lots was found in Peru. Three contracts of interest were identified there. Two wheat flour contracts were particularly important as they had been shipped several months earlier and offered an opportunity to check the stability of vitamin A over time. They were therefore likely to show losses of vitamin A. These stocks were only still available because there had been some delay in the monetization of wheat flour in Bolivia<sup>7</sup>. Sampling took place during October 1998 following the same protocol as was used in Peru. Contracts of interest were located in FHI warehouses in El Alto and Potosí where the bags were stacked in piles. In contrast to Peru, many of the bags had legible lot numbers although some had faded during handling. Seventy-two samples were collected with 37 samples of wheat flour from Contract No. VEPD 01635, 18 samples of wheat flour from Contract No. VEPD 01624, and 17 samples of bulgur from Contract No. VEPD 01619. Twelve bulgur samples from Contract No. VEPD 01619 were collected in the Potosí warehouse (Almacen 35011) where some stock was still available.

## C. Determination of Stability of Vitamins During Frozen Storage

In the course of this study samples of P.L. 480 commodities collected by SUSTAIN and foods prepared from them were kept in frozen storage at minus 20° C. It was not known to what degree vitamin A and vitamin C would degrade under those conditions. Ten samples of CSB and WSB that had been tested immediately after production were retested after frozen storage for the same time period used to determine stability under field conditions.

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<sup>7</sup> SUSTAIN retained Andreina Soria de Claros, a local Consultant to collect the samples in Bolivia. She was well known to USAID and the cooperating sponsor groups in Bolivia and had assisted with the Peru sampling.

The stability of the vitamins during frozen storage should serve as a baseline of the maximum possible retention. If, for example, a vitamin retention of 80% was found under frozen storage, a vitamin retention of 80% under field storage conditions would not be a serious concern because a higher retention would be unlikely under the best of field storage conditions.

## **D. Determination of Stability of Vitamins During Food Preparation**

### **Preliminary Laboratory Testing**

Prior to undertaking field testing, preliminary laboratory studies were conducted at Lancaster Laboratories to gain familiarization with the basic food preparation methods used for CSB and WSB. This testing also helped establish what vitamin retention levels to expect during field work.

In these tests, four different dilutions of CSB and WSB were prepared under conditions described in Appendix D. These foods represented beverages (8% CSB), gruel samples (14% CSB or WSB), pastes (20% CSB or WSB) and dumplings (41% WSB). The preparations were cooked in a heavy aluminum pot on an electric range. The cooking times, holding times, temperatures, and pH were recorded. Samples were removed from the cooking pot at the indicated times and put into a 2 oz screw cap plastic container. The containers were then put immediately on a bed of dry ice to freeze. Samples were kept frozen until tested for vitamin content within two weeks.

### **Field Testing**

The objectives of the field tests were to (1) document the typical food preparation methods used by food aid beneficiaries for CSB and WSB in both developing country and refugee situations and (2) to determine the vitamin C and vitamin A retention during those food preparation methods. CSB sampling took place in refugee camps in Tanzania; WSB sampling occurred in impoverished areas in Haiti. Taking into account the estimated variability of the WSB vitamin content, a member of the statistical subgroup calculated that a minimum of ten samples needed to be collected from the food prepared in Haiti.

With the assistance of the agencies distributing the food aid commodities (ADRA in Haiti and WFP in the refugee camps in Tanzania), SUSTAIN made appointments to meet with beneficiaries who use WSB or CSB regularly, at their homes. Community leaders (MCH centers in Haiti, “street” social workers in the refugee camps) asked several mothers if they would volunteer for the study. The only requirement was that they would be available for cooking at the time of the appointment with the appropriate ingredients. Our preliminary study had shown that in Haiti, the most commonly prepared WSB dishes were gruel and a vegetable broth with dumplings. In the Tanzania refugee camps the most commonly prepared CSB dishes were a gruel and *ugali*, a Swahili word referring to a stiff porridge. Upon being selected for the study, the mothers were free to choose the type of dish that they wanted to cook.

### **Methods of Sampling**

During the sampling appointments, we met with the mothers and gave them each an extra ration of the commodity taken from the special procurement bags, which were sampled just prior to cooking. The extra rations were identical in quantity to their regular rations (one-to-two weeks worth ration). Typically, the ration is consumed within two or three weeks of distribution. This is true for the beneficiaries in Haiti and in Tanzania.

During food preparation the ingredients and weights, cooking procedures, cooking times and temperatures, and pH measurements were recorded. The length of time that the WSB or CSB commodities were placed in a water solution prior to cooking was also recorded. The type and nature of utensils used and the type of fuel used to cook the food was recorded. Critical parts of the preparation were also photographed to record the procedure.

In both Haiti and Tanzania, mothers usually serve the food immediately after cooking. Therefore, as soon as the food was ready, a representative sample of the cooked food was placed in a four ounce plastic container. This was tightly screwed closed and placed in a cooler with frozen ice packs. The containers were put into a freezer within eight hours of collection. Freezer temperatures were measured to ensure that the samples were kept frozen at all times. The frozen samples were brought back to the U.S. in a cooler with ice packs and put in a freezer until collected by Lancaster Laboratories for analysis. A recording thermometer was placed in with the samples to verify that the samples were kept below 32° F at all times.

## E. Analytical Testing Methods

The dry WSB and CSB samples taken before and after cooking were analyzed for vitamin C, vitamin A, niacin and moisture content. The frozen CSB food samples from Tanzania were tested for vitamins C and A within two weeks of sampling. The frozen WSB food samples from Haiti were tested for these vitamins within three weeks of sampling. The analytical methods used are described in Appendix C and summarized in Table 7.

**Table 7. Summary of Analytical Methods Used**

Nutrient	Method	Range allowed for standard	% error
Vitamin A	Liquid Chromatography	1719-2173 IU/100g	9 %
Vitamin C	Fluorescent	108 – 121 mg/100g	11 %
Niacin	Colorimetric	22 - 27 mg/100g	20 %
Iron	Atomic Absorption	59 - 67 mg/100g	6 %

A NIST (National Institute of Standards and Technology) dry infant cereal reference was conducted with each set of daily tests. If the standard fell outside of the range shown in Table 7, the results were not used and the set was repeated. The allowable analytical error, as a percentage, is also shown in Table 7. The analytical error was also determined from the ten blind duplicate samples taken at the mills.

## F. Statistical Analysis Methods

A statistical software program was used to analyze data collected on production samples. This program calculates a number of descriptive statistics useful in analyzing production data including *production capability indexes* (Cp and Cpk) which are shown in the results. Histograms and control charts are provided in Appendix E.

The retention of vitamins A and C was determined by first establishing whether the data fit a normal distribution. If so, a Student T-test was used to determine if there was a significant difference between the two sets of samples. If the data was not normal, steps were taken to transform it to usable form. The data was then subjected to an analysis of variance test to determine the confidence intervals. The confidence level on each mean level was calculated in order to determine the significance of any difference between the two means.

With the FGIS samples, the retention of vitamin A in each lot was determined by the Student T-test on the difference between the level in the FGIS sample and the level in the recipient samples. When multiple lots had been collected and tested, the mean level of vitamin A in the whole plant production of a contract was compared to the mean level in the recipient samples. This served to make the analysis more robust.

## IV. FINDINGS & CONCLUSIONS

The procedures and methods discussed in the previous section proved to be highly appropriate range of concerns regarding the uniformity and stability of micronutrients in Title II commodities. The findings and conclusions shed light on the following questions:

- (1) What are the levels of the added micronutrients in the specific fortified food aid commodities at the point of production in the United States and how close do they come to meeting current standards or targets?
- (2) What is the uniformity of selected micronutrients in the commodities at production?
- (3) What is the stability (degree of retention) of vitamin A and vitamin C during shipping and storage?
- (4) What is the stability of vitamin A and vitamin C during food preparation?

Overall findings for all four nutrients and five commodities investigated revealed serious problems in meeting target levels and product uniformity at U.S. production facilities, and high vitamin losses were observed in the preparation of foods by program recipients, as summarized in Table 8. Relatively minor problems were found in losses in shipping and storage.

**Table 8. Summary of Problems of Selected Micronutrient Stability and Uniformity in Specific Food Aid Commodities**

Problem	Nutrient:	Corn Meal			Corn Soy Blend				Wheat Soy Blend				Wheat Flour			Bulgur	
		A	B3	Fe	A	C	B3	Fe	A	C	B3	Fe	A	B3	Fe	A	Fe
(1) Levels		3	—	3	1	2	3	3	3	3	3	—	1	—	—	1	3
(2) Uniformity		3	—	3	1	1	3	1	3	3	3	—	1	—	—	1	2
(3) Shipping & Storage Stability		—	—	—	2	3	3	3	1	3	3	—	3	—	3	3	3
(4) Food Preparation Stability		—	—	—	1	1	3	3	1	1	3	3	—	—	—	—	—

Key: 1 – Serious problem detected; 2 – Minor problem exists or may exist; 3 – No problem detected; A – vitamin A; C – vitamin C; B3 – niacin; Fe – iron; “—” – Data was not collected or inconclusive

### A. Micronutrient Levels During Production

#### Overview

The actual levels of micronutrients in the fortified P.L. 480 food commodities at the point of production is of primary importance if nutrients are to reach the food aid recipients. The two different types of samples from production plants provided different but complementary and mutually reinforcing types of results. The first were individual samples taken over a two to three day period during a production run and reveal how well expected levels are met and how well levels are maintained from bag to bag. They represent conditions during a short slice in time in the production history of a particular plant. There is no way of definitely knowing whether any uniformity and compliance problems observed during this period were temporary or long term, except through the equipment and design of plants. The second test was an analysis of FGIS composite lot samples. This analysis provided a good indication of how closely the plant met the minimum specification or target for that lot, but it did not indicate the variability within that lot. The results show the variability between lots, (which is not provided in the first type of sample testing), and give a much better picture of how well a plant meets current or proposed fortification standards as they represent a much larger quantity of product produced over a longer time interval. Regular testing of these composite samples is one option to better control fortification practices.

#### Results

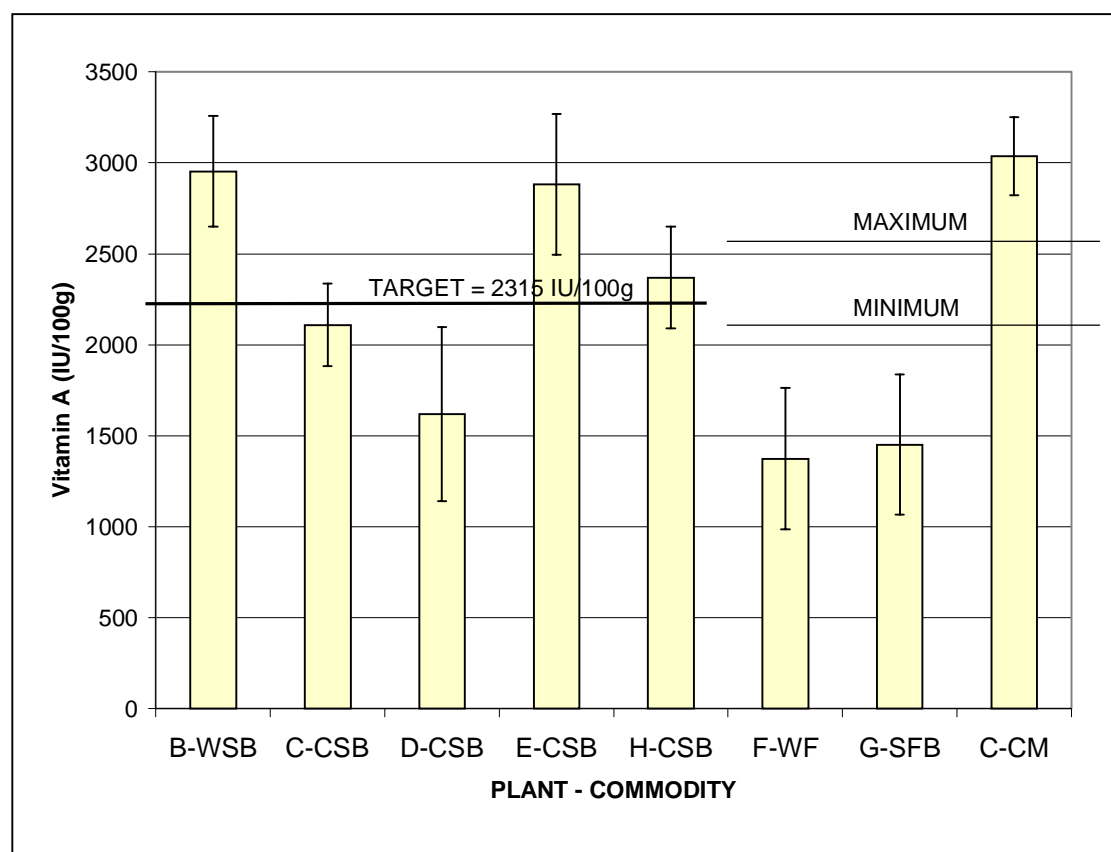
**Some plants have serious problems meeting the target levels of vitamin A in CSB and the minimum standard for vitamin A in wheat flour and bulgur.** One CSB plant also had problems in meeting target levels for vitamin C. None of the sampled plants had problems meeting minimum levels of niacin or iron.

### Samples Collected at Plants

Vitamin A was tested in the production runs at eight different plants. Three of those showed mean levels well below the minimum standard or target, as illustrated in Figure 1. CSB plant D had a mean vitamin A level at 70% of target. Plant F showed a mean vitamin A level in wheat flour at 57% of the minimum standard. Plant G had mean vitamin A levels at 60% of the minimum. Corn meal plant C showed a mean vitamin A level above the maximum.

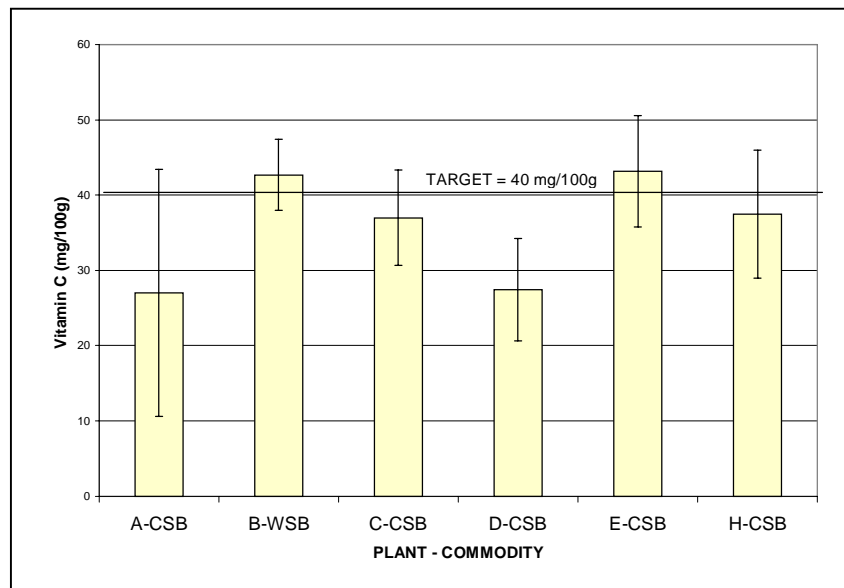
One of the six production runs in which vitamin C was tested had a mean vitamin C value well below the target, i.e. CSB from plant D was 69% of the target. Plant A also had vitamin C levels below the target but it was within one standard deviation due to the large variability at that plant. None of the four plants tested for niacin (Figure 3) or the six plants tested for iron (Figure 4) showed low levels of those two micronutrients.

**Figure 1. Summary of Vitamin A Results from Production Plants<sup>8</sup>**

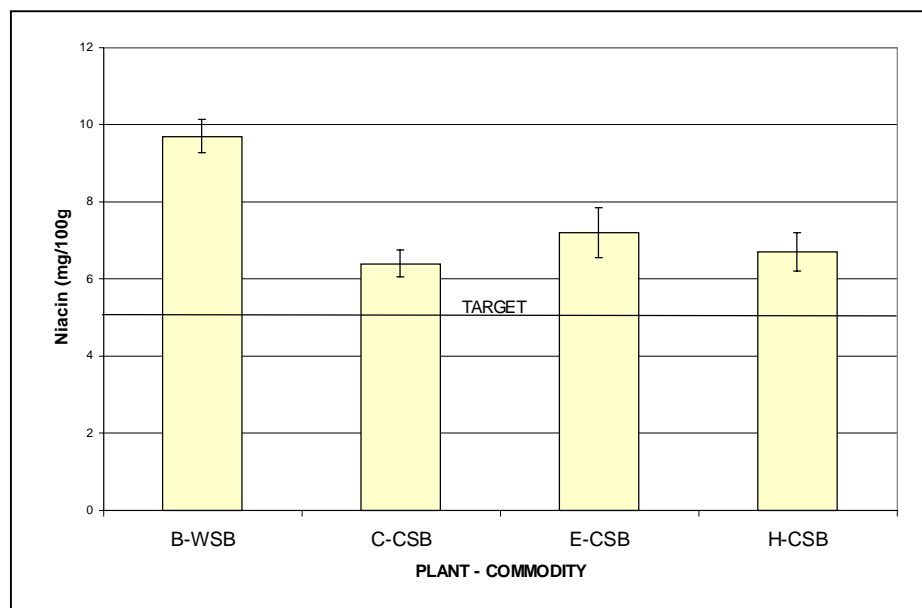


<sup>8</sup> Each bar in Figures 1 through 4 shows the mean micronutrient level of roughly 48 samples of a particular commodity from a particular plant. The vertical line on each bar shows  $\pm$  standard deviation for that set of data centered around the mean. A target level line is shown for the blended foods (CSB and WSB). Minimum-maximum lines, or a single minimum line, are shown for the fortified processed foods. Full results are given in Appendix E.

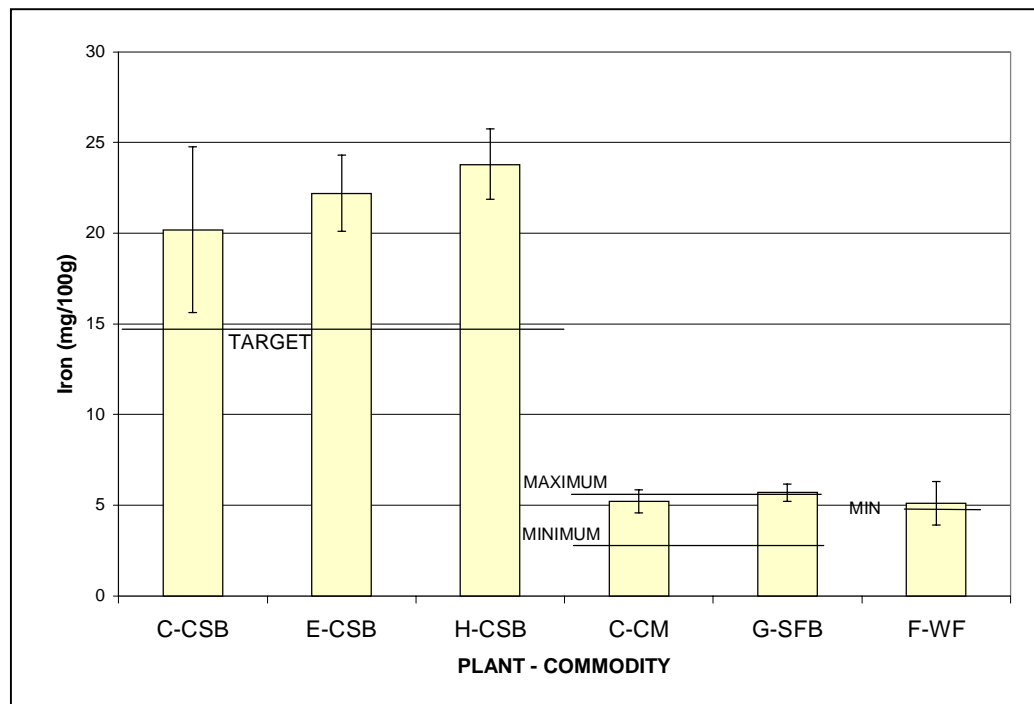
**Figure 2. Summary of Vitamin C Results from Production Plants**



**Figure 3. Summary of Niacin Results from Production Plants**



**Figure 4. Summary of Iron Results from Production Plants**



### FGIS Samples

The results on the FGIS composite lot samples, summarized in Tables 9 and 10 with full results in Appendix D, show **a serious problem in plants meeting the current minimum vitamin A specification in wheat flour and bulgur**. This problem is of greatest concern in the bulgur samples from Plant L, where the vitamin A levels were less than a quarter of the minimum specification.

**Table 9. Summary of Vitamin A Assays on FGIS Composite Lot Samples of Wheat Flour**

Plant	No. of Samples	Mean (IU/100g)	Standard Deviation (IU/100g)	COV (%)	Minimum (IU/100g)	Maximum (IU/100g)	Mean as % of Min. Spec.
I	6	1982	190	9.6	1720	2220	90%
J	6	1223	112	9.2	1090	1350	56%
F	6	1205	186	15.4	920	1420	55%
I	18	2157	180	8.3	1860	2420	98%
K	43	1674	287	17.1	810	2170	76%
M	49	1660	166	10.0	1090	1980	75%
-	7	1447	129	8.9	1250	1640	66%
-	3	1380	130	9.4	1200	1500	63%
-	15	1505	136	9.0	1250	1770	68%
-	1	1450	N/A	N/A	N/A	N/A	66%
-	1	1830	N/A	N/A	N/A	N/A	83%
Total	155	1669					76%



The wheat flours were produced by a number of different flour mills. While uniformity between the flour lots was generally good, vitamin A levels in wheat flour were below the minimum specification. This could be due to some loss during processing and prior to testing, but it could also be due to improper adjustment of the vitamin premix feeders.

**Table 10. Summary of Vitamin A Assays on FGIS Composite Lot Samples of Bulgur**

Plant	Number of Samples	Mean (IU/100g)	Standard Deviation (IU/100g)	COV (%)	Minimum (IU/100g)	Maximum (IU/100g)	Mean as % of Min. Spec.
L	3	542	167	30.8	370	840	25%
L	14	525	72	13.7	349	650	24%
L	7	374	55	14.7	320	470	17%
G	20	2348	566	24.1	1630	3520	107%
G	6	1190	116	9.8	1010	1380	54%
L	6	598	87	14.6	470	760	27%

There are only two plants that produce bulgur and soy fortified bulgur. The vitamin A results on FGIS samples from four contracts of bulgur produced by Plant L showed levels far less than what it is supposed to contain. There was also high variability between the lot samples. The FGIS results indicate that Plant G was also having a problem in achieving specified levels of vitamin A in bulgur.

### Plant G Bulgur Studies

Plant G management was not pleased with the results of the initial soy fortified bulgur samples collected at their plant. As a result, they took a number of steps to improve the situation. The first action was to turn off the air suction at packout, in case the vitamin A was being sucked out of the bulgur. This resulted in a dusty packout area. The other action was to increase the addition rate of the vitamin/iron premix by about 50% to make up for the missing vitamin A. This was a temporary measure since it was costly to the plant and resulted in higher than necessary levels of iron and the other vitamins being added. The mill asked their vitamin/iron premix supplier to provide a stickier, less dusty premix for fortifying bulgur. The vitamin A results obtained from the initial run of this new premix are given in Appendix G and summarized by sets 2 and 3 in Table 11. A SUSTAIN representative was present during this test run.

Five runs were made of fortified bulgur with two different kinds of vitamin premixes added at different addition rates. The first two sets were made with conventional powdered vitamin/iron premix. The next three sets were made with a sticky/granulated vitamin/iron premix using wheat germ as the carrier. During each production run, samples were taken from the top of the bin going into the packer, from the bag just after filling, and from the sealed bag at the top, middle and bottom sections.

When the conventional premix was added at 50% over label directions, the mean vitamin A content in the bag was about what would be expected from the addition, and was above the target. With the new premix, an addition of 10% over label claim yielded a product that met the target. The level of vitamin A in the bottom of the bags was 19% higher than that in the top portion of the bag, but this difference was not statistically significant.

**Table 11. Summary of Vitamin A Levels in Bulgur at Plant G**

SET	Type of Samples	Feeder Setting	Mean Vitamin A (IU/100g)	Number of samples	Percent of Minimum	COV
1	Bag		1451	39	66 %	27 %
2	Bag	150%	3177	3	144 %	
3	Bag	110%	2620	3	119 %	
4	FGIS Composite		2348	20	107 %	11 %

Plant G continued to use this new premix, at 5% over label directions. This worked quite well as shown by set 4 results in Table 11. They monitored the vitamin A levels by doing their own testing using the standard AACC Colorimetric procedure. Their results agreed quite well with those from Lancaster Labs. For example, their mean level on set 3 in Table 11 was 2783 IU/100g and 2367 IU/100g on set 4. Unfortunately, the latest set of FGIS samples from plant G that were tested, (See Table II), indicate a drop in the vitamin A levels below target, showing the need for continued vigilance.

## Conclusions

**The failure to meet minimum standards of vitamin A is a serious problem.** Low initial vitamin levels have potentially damaging consequences in that it results in the delivery of continued low levels of needed micronutrients. The USDA can solve this problem by having the FGIS monitor micronutrient levels by testing the regular composite lot samples, as is being planned. Ensuring that each lot is properly fortified, (as determined by a micronutrient “indicator” such as vitamin A), and meets some minimal standard, would help guard against recipients suffering from micronutrient deficiencies, providing they are receiving adequate rations and vitamin losses are not excessive.

The fortified blended foods (CSB and WSB) currently have micronutrient “*process standards*,” which function as *targets*. This allows the micronutrient content to vary in either direction around the target. A minimum standard is needed in order to enforce compliance. The minimum level proposed for vitamin A in CSB and WSB is 80% of the target, or 1850 IU/100g. Of the five productions of blended foods, CSB from plant D would have failed to meet this proposed minimum for vitamin A.

**The fortified processed foods currently have minimum micronutrient standards that are not being met for vitamin A.** This study uncovered several examples of products failing to meet existing fortification standards. For example, both FGIS samples and samples collected in the field showed that the vitamin A content in bulgur produced by plant L was low enough to demand immediate correction. In addition, wheat flour produced by a number of different plants also showed low vitamin A levels.

The reason for low vitamin A in fortified processed foods is not clear. There are a number of possible causes including low levels of vitamin A in the premix, loss of vitamin A activity in the premix during storage, not enough premix being added at the mill, loss and oxidation of vitamin A in the flour during pneumatic transfer, or any combination of these factors.

The results of the analysis of wheat flour in Bolivia showed virtually no loss of vitamin A after nine months of storage so **it is unlikely that vitamin loss after milling and packaging is the cause of this problem.** However, it may be that some of the vitamin A is rapidly oxidized and lost during the milling process when it is exposed to air during feeding and pneumatic conveying. The more the vitamin is exposed to air, the greater the loss. This could also be a function of the quality of the coating and antioxidation system in the vitamin A palmitate (250SD type) product being used. A product of poor quality may offer little protection against air oxidation during milling.

The vitamin A content of the vitamin premix samples collected were all close to specifications, as shown by the results in Appendix D. There was no evidence that the low vitamin levels seen in some of the commodities was a result of a faulty vitamin premix containing low initial levels of vitamin A. More work needs to be done to

determine why some of the processed foods contain low initial levels of vitamin A so that the problem can be corrected.

The low vitamin A levels at production seem to be more of a problem with wheat flour and bulgur than with CSB and WSB. Only one production of CSB (Plant D) was really low in vitamin A, and that appeared to be caused by faulty premix addition rates since the vitamin C was also low. Their problem may be primarily due to an incorrect feeder adjustment. The nutrient feeders at Plant D were old and worn and may not have been able to hold their calibration or deliver a consistent rate of product. The equipment for metering nutrients at Plants C, E and H were newer, well maintained, and correctly calibrated. Plant H showed good uniformity with all the micronutrients except for vitamin C.

The vitamin A in corn meal from Plant C was above the maximum of the minimum-maximum range. This brings into question the utility of having so narrow a range, or having a maximum at all, since it is hardly larger than the normal process variation or even the analytical error, as shown by the allowable error in the NIST standard.

## B. Micronutrient Uniformity at Production

### Overview

Some reasonable uniformity<sup>9</sup> in the distribution of added micronutrients within fortified P.L. 480 food commodities is needed if the diets of food aid recipients are to contain a fairly constant level of these nutrients. There were three types of micronutrient uniformity investigated in this study: (1) within bag uniformity, (2) between bag uniformity, and (3) the uniformity between lots. The within bag uniformity was determined by sampling bags at production and recipient sites at three locations within the bag: top, middle and bottom. Between bag uniformity was determined by sampling roughly 48 different bags over a two to three day production run. Between lot uniformity was determined by testing the composite FGIS lot samples.

Full results for each plant can be found in Appendix D. The analytical results of samples collected at the plants, as well as the distribution histograms and control charts for the micronutrients for each consecutive sample, are shown in Appendix E and help to visualize how the nutrient value varied over the production run. Figures 1 through 4 also show one standard deviation above and below the mean.

### Results

**Within bag uniformity was good.** Student T- tests showed no significant difference ( $P>0.05$ ) in micronutrient levels from top to bottom of the bags of samples taken at production. The only suggestion of possible difference or segregation was in the plant bulgur samples where the samples from the top of the bag were slightly lower in vitamin A content from the middle or bottom of the bag.

Within bag variation after shipping and handling was determined by sampling from bags of CSB in Tanzania and WSB in Haiti at three different bag locations (top, middle and bottom). There was variation between samples taken from the three bag locations but the variability was consistent throughout the bag, indicating that there was no systematic stratification or concentration of the vitamin within one part of the bag.

Samples were also taken from different bag locations for bulgur and wheat flour in Peru and Bolivia. There did appear to be lower levels of vitamin A in the top portion of bulgur bags, where the FGIS sample would have been taken, but these differences were not statistically significant, so no firm conclusion can be made. For example, in one bulgur contract in Peru the eight samples from the top portion of the bag averaged 1225 IU/100g while the middle and bottom averaged 1609 and 1777 IU/100g respectively. In Bolivia the samples taken from the middle and bottom of the bags were 14% higher in vitamin A content, but the difference was not statistically significant. The vitamin A content of the wheat flour samples showed no difference by bag sample location.

**The CSB plants had generally poor uniformity for vitamins A and C.** Only one CSB plant (C) had poor uniformity for iron ( $COV = 23\%$ ) and all the plants tested for niacin showed good uniformity for that vitamin. CSB

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<sup>9</sup> The variability of a set of samples can be used as an inverse measure of the degree of uniformity. The standard deviation is a measure of variability. This can also be expressed as the coefficient of variation (COV) which is the standard deviation as a percentage of the mean.

Plant A had the worst uniformity with a COV of 61% for vitamin C. CSB plant D had high vitamin A variability (COV = 30%). CSB Plant C, which had good uniformity for vitamin C and niacin, was poor for iron (COV = 23%), which is added separately from the vitamins.

**The WSB plant had good uniformity** for all the micronutrients tested, which is not unexpected since it is a batch operation as opposed to the continuous fortification used in all the CSB plants.

**The wheat flour and bulgur plants had poor uniformity for vitamin A.** The COV for vitamin A at bulgur plant G was 27% and 26% at wheat flour plant F, which also had poor uniformity for iron (COV = 23%).

**The vitamin C and A between bag variation found in the delivered CSB and WSB was no worse than that found at production and often slightly better.** The variability of vitamin A in the bulgur samples collected was much greater than that in wheat flour. The COV for wheat flour in Peru was less than 8%, which is quite good, and 8 to 12% for those collected in Bolivia. Bulgur samples had a COV over 25%.

**The uniformity of vitamin A between lots was generally good in wheat flour but not in bulgur.** Seven of the nine different wheat flour sets tested had COVs of 10% or under (Table 9). Of the six sets of bulgur tested, all but one had COVs over 10% (Table 10).

## Conclusions

The within bag uniformity is generally a function of segregation during packing or separation during handling and storage. Fine powder products, like wheat flour and CSB, are less likely to be subject to those problems than the coarser products like bulgur, particularly when packed in large bags of 50 to 100 lbs as these are. **This study showed there is no serious problem with segregation or separation of the micronutrients after packout.**

**The results on this study showed there is room for improvement in the uniformity of added micronutrients.** It is difficult to say what level of micronutrient variability in fortified foods is needed or acceptable. Clearly, the wide variation seen in CSB Plant A, where vitamin C levels ranged from near zero to several times the target value, is unacceptable by any standard. At the other end of the scale, WSB Plant B and corn meal Plant C showed excellent uniformity, but the same degree of uniformity may not be possible in other plants using processes and equipment more prone to causing variability.

The problem of poor uniformity from bag to bag will be difficult to monitor since the FGIS does not routinely collect or test individual samples to determine uniformity, as was done in this study. Perhaps the best way to make improvements in this area is by proper application of a Total Quality Systems Audit (TQSA). Under that program plants will have to demonstrate they have the proper equipment, design and procedures necessary to produce a uniform product.

Plants may be more motivated to improve their fortification systems and equipment if they are required to meet minimum micronutrient levels for one or more indicators as is recommended by this report. This will result in improved uniformity since producing companies will take pains to decrease low levels for fear of being fined or having a product lot rejected, while avoiding excessively high levels for economic reasons. This will give a competitive advantage to those plants able to maintain the best uniformity.

While poor uniformity of micronutrients in fortified P.L. 480 food commodities is a concern, it is not as serious a problem as the low levels of micronutrients found in some of the products. Correcting the first problem of compliance will lead to an improvement in uniformity as well. Therefore, efforts should be directed at making sure the levels of micronutrients contained in these products at the point of shipment are adequate since that is the easiest to achieve and the most important from a nutritional health standpoint.

## C. Stability of Micronutrients After Shipping and Storage of Commodities Overview

The micronutrients added to fortified P.L. 480 food commodities would provide limited benefit to food aid recipients if most of those nutrients are lost from the food during normal shipping and storage of the dry

commodities. One of the primary objectives of this study was to determine if the large loss of vitamins A and C during shipping and storage suggested by Atwood et al (3) and others was, in fact, a problem that needed to be solved. This was done by comparing the vitamin A and vitamin C levels in commodities prior to shipping to those in the same commodities at the recipient site.

### Vitamin Stability in the Blended Foods

**No serious problem with the stability of vitamin C was found in the dry commodities (CSB and WSB) during shipping and storage. There was some loss of vitamin A.**

The full analytical results on the CSB samples collected in India and WSB samples from Haiti are given in Appendix D. The following Tables 12 and 13 summarize the results. This stability component of the study does not include data from Tanzania because the CSB pilot production run sent to Tanzania did not contain sufficiently uniform distribution of vitamins to allow for an efficient test of stability.

There were two different batches of WSB tested in this study. One had the conventional level of vitamin C added and the other had an experimental high level added. The two batches were made in the same plant one just after the other, but a different vitamin premix was used for each batch. Since they were from different premix suppliers, the vitamin C and vitamin A sources were different as well.

The WSB sent to Haiti with the conventional level of vitamin C showed a vitamin C retention of 87% after nine months, which is significant ( $P<0.01$ ) but does not indicate a large enough loss to be concerned about. The WSB with the high level of added vitamin C showed a small gain, but it was not significant ( $P>0.05$ ), so the conclusion would be that no vitamin C was lost in this product after nine months of storage.

The samples of CSB collected in India, which contained conventional levels of vitamin C, came mainly from two lots (AA and AB) produced on the same day. The mean vitamin C in those samples compared to the production mean of the same two lots showed a very slight gain that is not significant ( $P>0.05$ ). Again, the conclusion would be that no vitamin C was lost in dry CSB after five months.

**There were significant ( $P<0.01$ ) losses of vitamin A in both WSB and CSB.** WSB showed a vitamin A retention of 62% after nine months and 86% in the CSB after five months. These losses were much greater than the changes shown by the same samples under frozen storage, so the losses are due to field storage conditions. There was no difference in the retention of vitamin A in WSB with the two different premixes (the one with the conventional vitamin C level and the one with the high vitamin C level). The main determinant of vitamin A retention appears to be the length of storage, although it may be that vitamin A is more stable in CSB than it is in WSB, a conclusion supported by the frozen storage studies.

**Table 12. Vitamin C and A Retention in CSB and WSB Based on Comparison of Mean Levels**

Product	Lots	Vitamin C Means			Vitamin A Means		
		at plant (mg/100g)	at recipient (mg/100g)	Retention (%)	at plant (IU/100g)	at recipient (IU/100g)	Retention (%)
WSB	Conventional C	42.7	37.1	<b>** 87.0%</b>	2954	1820	<b>** 61.6%</b>
WSB	High C	76.2	79.7	<sup>NS</sup> <b>104.6%</b>	2410	1578	<b>** 65.5%</b>
CSB	lots AA & AB	38.4	39.4	<sup>NS</sup> <b>102.7%</b>	2165	1854	<b>** 85.6%</b>

**\*\*** Significantly different from 100% retention at  $P<0.01$  indicating loss.

<sup>NS</sup> Not significant different from 100% retention at  $P>0.05$  indicating no change.

**Table 13. Vitamin C and A Retention in WSB Based on Comparison of Paired Samples**

Lots	Vitamin C Means			Vitamin A Means		
	at plant	at recipient	Retention	at plant	at recipient	Retention
	(mg/100g)	(mg/100g)	(%)	(IU/100g)	(IU/100g)	(%)
Conventional C	42.9	37.5	<b>** 87.6%</b>	2881	1830	<b>** 63.5%</b>
High C	75.9	80.0	<sup>NS</sup> <b>105.4%</b>	2419	1589	<b>** 65.7%</b>

\*\* Significantly different from 100% retention at P<0.01 indicating loss.

<sup>NS</sup> Not significant different from 100% retention at P>0.05 indicating no change.

### Stability of Vitamins in Frozen Samples

The results show little change in vitamins during frozen storage. There was no significant loss of vitamin C in CSB after five months storage or in WSB after nine months, nor was there any loss of vitamin A in CSB. There was a small but significant (P<0.05) loss of vitamin A in WSB after nine months storage.

**Table 14. Vitamin Retention in Frozen Samples**

Product	Storage Time	Vitamin C Means			Vitamin A Means		
		at Production	after Freezing	Retention	at Production	after Freezing	Retention
	(months)	(mg/100g)	(mg/100g)	(%)	(IU/100g)	(IU/100g)	(%)
WSB	9	53.9	54.2	<sup>NS</sup> <b>100.6</b>	2651	2448	<b>* 92.3</b>
CSB	5	39.0	37.1	<sup>NS</sup> <b>95.2</b>	2143	2244	<sup>NS</sup> <b>104.7</b>

\* Significant different form 100% retention at P<0.05 indicating small loss.

<sup>NS</sup> Not significant different from 100% retention at P>0.05 indicating no change.

### Vitamin A Stability in Wheat Flour

**The vitamin A stability in wheat flour was shown by this study to be surprisingly good.** There was virtually no loss of vitamin A after nine months of storage.

Wheat flour samples were collected at a CARITAS warehouse in Lima, Peru, and at the FHI El Alto warehouse in La Paz, Bolivia. Full results are shown in Appendix D. In Peru multiple samples were taken from three different lots. Vitamin A content was compared to that of the retained FGIS samples for each lot, as shown in the following table. The small drop in vitamin A was statistically significant at the 5% level for one lot but not the other two. There was only a one month period between the time of testing the retained FGIS samples and those collected at the recipient sites.

**Table 15. Vitamin A Retention in Wheat Flour in Peru**

Lot	Number of Samples	Vitamin A Means (IU/100g)		
		FGIS	at recipient	Retention
12	5	1406	1570	<b>* 89.6%</b>
13	3	1290	1350	<sup>NS</sup> <b>95.6%</b>
14	5	1242	1340	<sup>NS</sup> <b>92.7%</b>

\* Significantly different from 100% retention at P<0.05 indicating loss.

<sup>NS</sup> Not significant different from 100% retention at P>0.05 indicating no change.

**Table 16. Vitamin A Retention in Wheat Flour in Bolivia**

Contract	Number of Samples	Vitamin A Means (IU/100g)		Retention
		FGIS	at recipient	
1624	18	2086	2023	<sup>NS</sup> <b>97.0%</b>
1635A	11	1731	1763	<sup>NS</sup> <b>101.8%</b>
1635B	25	1672	1646	<sup>NS</sup> <b>98.5%</b>

<sup>NS</sup> Not significant different from 100% retention at  $P>0.05$  indicating no change.

Two contracts of wheat flour were found in Bolivia. They had been there for a considerable amount of time since the time between testing the retained FGIS samples and the samples collected in Bolivia was nine months. Surprisingly, there was virtually no loss of vitamin A in that period, as shown in Table 16, which compares the vitamin A content in matched lots of product. The large number of samples (54 total) involved in this analysis gives a high level of confidence to these results.

### Vitamin A Stability in Bulgur

**The vitamin A stability in dry bulgur appears to be acceptable**, but the data collected in this study is not as convincing as it is for wheat flour because it only covered a one month storage period and involved very low levels of vitamin A in the products out of the plant.

Same-lot samples of one bulgur contract produced by plant G, as indicated by the same production date stamped on the bags, were collected at the CARITAS warehouse in Peru. These were collected in two sets: seven from one pallet and 14 from different locations around the warehouse. There was a large variability in the vitamin A results on the first set of 7 samples, ranging from a low of 780 IU/100g to a high of 3510 IU/100g. The second set was more uniform. The vitamin A retention was 135%, an increase, but this was not statistically significant because of the high variability. Removing the first set, the retention was 116% but this was not significant.

Six samples from two lots of another bulgur contract produced by plant L were collected from the CARITAS warehouse. The vitamin A content of this contract was very low to begin with making it more difficult to determine loss. Also, while there were vitamin A results on FGIS samples from this contract, they were not from these lots. In comparing the results from the Peru samples which averaged 613 IU/100g to the six FGIS lot samples, which averaged 514 IU/100, there was a vitamin A retention of 119% which is not statistically significant. This indicates there was no loss of vitamin A in these samples.

Samples of bulgur were collected at two different warehouses in Bolivia. All were from the same contract produced by Plant L. Vitamin A levels on this contract as determined by the retained FGIS samples were very low, only a quarter of the minimum specification. The mean vitamin A content of the 16 collected samples was virtually the same as that of the retained lot samples, indicating no loss after nine months.

### Conclusions

This study shows that the low levels of vitamins found in fortified P.L. 480 food commodities at recipient sites overseas by Atwood et al (3) were largely the result of the commodities having low levels of vitamins at the start. While there was some loss of vitamin A in WSB after nine months, showing a 63.5% retention, there was little loss of vitamin A in wheat flour and bulgur or vitamin C in CSB and WSB during shipping and storage.

This may be due to the fact that the vitamin A particles most susceptible to oxidative destruction, those with a poor coating, are destroyed early on during manufacturing. The remaining particles are better protected and have better stability. This could account for the observed drop in vitamin A during production and the good stability afterwards.

There is an interesting connection between plant B making WSB, plant F making flour and plant L making bulgur. All three plants are supplied by the same fortification premix supplier, which did not provide premix to any of the other production sites sampled in this study (except for plant A where the vitamin A content was not tested because



of the wide variability). Vitamin A levels in the bulgur and flour were low. This may be due to the poor quality and stability of the vitamin A used by both plants. Both plants were pneumatic systems, so the vitamin A may have been lost to oxidation when it came into contact with air in the mill. There was no loss of vitamin A in plant B, however, which uses a gravimetric batch system and thus gives limited exposure to the vitamin A in the mill. The WSB from plant B did show vitamin A loss during subsequent handling and shipping. This loss might then be due to the WSB product having been fortified with a poor quality vitamin A product. The WSB may not have shown the same degree of loss if it had been fortified with the same source of vitamin A used in the CSB products.

**The conclusion from these results is that vitamin loss in the dry commodities is statistically significant, but it is not a serious overall problem.** The one-third loss of vitamin A found in WSB nine months after production was the largest loss observed, but this level of loss is within the expected vitamin A loss endured by the US food industry. WSB makes up a relatively small proportion of processed food aid, and the problem probably could be remedied by the manufacturer using a more stable source of vitamin A. There is no need to change the packaging, lower the moisture content or implement any of the related actions that have been proposed. Any such action would likely be expensive and ineffective. The one action recommended is that the mills and premix manufacturers make sure the vitamin A they use is of good quality and meets the stability standards specified by the USDA.

## D. Stability of Selected Micronutrients During Food Preparation

### Overview

The final concern regarding micronutrient fortification of P.L. 480 food aid commodities is that the added vitamins survive the cooking processes typically used by the recipients. Laboratory studies were run on typical food preparations of CSB and WSB to become familiar with their cooking properties and to estimate levels of expected vitamin losses. This was followed by field studies to determine the retention of vitamins A and C during normal food preparations of CSB and WSB as a normal part of Title II programs in two countries.

### Laboratory Studies

It was noticed in the laboratory trials that the same concentration of WSB is initially thicker than CSB in cold water, but that during cooking the CSB thickens more than WSB does. This is probably because CSB is less fully gelatinized than WSB, which makes CSB a little easier to prepare since the mixing during cooking is not as difficult. Cooked CSB had a milder taste than WSB, which can have some bitterness due to the wheat protein concentrate.

The retention of the vitamins C and A in the food at various stages of cooking and holding times are shown in Appendix D. These were calculated from the amount of vitamin that was present in the CSB or WSB corrected for its dilution.

WSB showed a vitamin C loss of approximately one-third just from the addition of water. **The final retention of vitamin C in the WSB gruel and paste was 70% to 50%.** CSB showed a higher vitamin C retention in beverages and gruel of around 85%. The WSB dumplings showed a lower vitamin C retention, similar to what was found in the field studies, and a steady loss over cooking time. This suggests that the water-soluble vitamin C is leached out during cooking. The vitamin C lab retention levels were higher than those found in the field studies. There are many differences between the field and laboratory conditions that may account for this, one being the rapid freezing of the laboratory samples compared to those in the field.

A second set of tests was run to determine the effect of simply wetting the CSB/WSB. The results, shown in Appendix D, do not indicate much of an effect but heating the wetted material resulted in a final vitamin C retention of around 88%.

### Cooking Methods Observed in Field Studies

These studies were conducted in Haiti where WSB was prepared at home and in refugee camps in Tanzania receiving CSB. All preparations were cooked in an aluminum pot over charcoal or a wood fire. All dishes had a pH of 6, with two exceptions where the pH was 7.

**Gruels:** Gruel is the most commonly prepared food observed for both CSB and WSB, accounting for 24 out of the 59 samples collected. On average, 14 grams of CSB or WSB are used per 100g of liquid to prepare gruel. Table 18 summarizes the vitamin C and vitamin A retention in the cooked food samples. A typical gruel was prepared by simply boiling CSB or WSB in water. The CSB/WSB was normally mixed with a portion of cold water to form a slurry while the rest of the water was brought to a boil. The slurry was then added to the boiling water and stirred. The mixture was brought again to a boil and allowed to simmer for a few minutes. The normal total cooking time for WSB gruel was  $19 \pm 5$  minutes in Haiti and  $12 \pm 6$  minutes for CSB gruel prepared in the refugee camps (cooking times are shown as the mean  $\pm$  one standard deviation).

**Dumplings in Haiti:** These dough dumplings, made of WSB and salt water, were shaped like fingers and then added to a vegetable broth, sometimes with meat or fish. The normal total cooking time for WSB dumplings was  $18 \pm$  minutes. For the sampling of this dish, the dumplings and vegetable broth were added together in one pot. However, the dumplings were collected as samples without vegetable or broth.

**Ugali in Tanzania:** Ugali is a stiff paste comprised of CSB and water that accompanies another dish called sauce. The sauce is usually prepared with beans and vegetables such as tomatoes, onions and cabbage. To make ugali, a small amount of water was brought to a boil. A portion of this water was removed just before it reached the boiling point and mixed with the CSB in another bowl into a thick dough. This dough was added to the boiling water and stirred for a few minutes to form a dry thick paste. The average total cooking time for CSB ugali was  $5 \pm 1$  minutes.

**Table 17. Summary of Food Preparation Samples Collected in Selected Countries**

WSB in Haiti	Number of Samples	CSB in Tanzania	Number of Samples
High vitamin C	5 Gruel 5 Dumplings	High vitamin C	7 Gruel 4 Ugali
Conventional vitamin C	4 Dumplings 3 Gruel	Conventional vitamin C	9 Gruel 1 Ugali

A batch of CSB was fortified with higher vitamin C level (90 mg/100g) than the conventional level added (40 mg/100g). Rather than one level of 90 mg/100g, the CSB used for the food preparation had four levels of fortification (68, 93, 140, and 160 mg/100g). The unexpected wide variation in the levels of fortification indicated a uniformity problem with fortification at the U.S. processing plants. It also provided the opportunity to determine the effects of different concentrations of vitamin C upon vitamin C retention in CSB after it was cooked in the field.

### Retention Levels in Cooked Foods

#### Large losses of vitamins C and A in both CSB and WSB occurred during normal food preparations.

Retention levels are presented in Table 18. Vitamin C retention in the gruel, dumplings and ugali samples averaged 30% for the WSB and CSB with the conventional level of vitamin C. For the commodities with high levels of vitamin C, the vitamin C retention averaged 58% for CSB and 55% for WSB.

Five out of nine gruel samples made from CSB with the conventional vitamin C levels showed vitamin C content to be below the level of detection of 1 mg/100g. The magnitude of the vitamin C loss for CSB was inversely proportional to concentration: the higher the level of vitamin C in the dry commodity before cooking, the greater the retention. This would be explained by the fact that vitamin C is less stable in diluted solutions than in more concentrated ones, particularly at pH 7 (4). The type of preparation did not have a significant effect on the vitamin C retention for WSB and for CSB preparations with high level of vitamin C.

**Table 18. Vitamin A and Vitamin C Retention during Food Preparation**

Commodity	Vitamin C level	Preparation type	N	Vitamin C	Vitamin A
Average percent retention					
Corn Soy Blend	Conventional	Gruel	7	25%	46%
		Ugali	1	51%	83%
	High	Gruel	6	58%	47%
		Ugali	4	55%	89%
Wheat Soy Blend	Conventional	Gruel	3	27%	46%
		Dumpling	4	18%	65%
	High	Gruel	5	32%	46%
		Dumpling	5	33%	77%

As expected, vitamin A had better retention than vitamin C during cooking. The vitamin A retention averaged 46% for the gruel samples and 70 % for the ugali and dumplings. The retention of vitamin A was significantly ( $p < .01$ ) better in the drier ugali and dumpling preparations than in gruel with higher moisture content.

The reported time variables were 1) the time that the commodity spent in a slurry comprised of the commodity and 2) water before cooking and the cooking time. They did not have significant effect ( $P>0.10$ ) on the retention of either vitamin C or vitamin A.

## Conclusions

**Large cooking losses of vitamin A and vitamin C were found during normal food preparation procedures used on CSB and WSB.** One-third to one-half of the initial vitamin C content was retained. Less than one-half of the initial vitamin A content was retained during preparation of gruel, the most commonly used preparation to feed young children. A better retention of vitamin A (70%) was observed for drier preparations (ugali and dumplings).

These large cooking losses are not unexpected. They are in line with past studies on similar cooking methods. The results make evident the need for more stable forms of vitamin A and C that are better able to withstand cooking. There are heat stable vitamin C products available but they have not been tested in CSB and the best ones have yet to be approved for human consumption. Currently, there is no form of vitamin A available that has a better cooking stability than the 250SD type product currently specified, but there are probably differences in the stability of the different commercial forms that are being used.

Food companies would not add vitamin C to products similar to CSB that are normally cooked, recognizing that most of the vitamin would be destroyed. Instead, they add it to foods like ready-to-eat breakfast cereals and fruit juices where vitamin stability is less of a problem since they involve no cooking. This is not an option with P.L. 480 commodities currently supplied to food aid programs, since they all have to be cooked. The one exception is instant corn soy blend. It contains fully gelatinized corn meal so it could be prepared by mixing with warm water. This product has been developed but is not in current use. This could be a result of the concern of possible contamination if the water used is not potable or not boiled.

It may be that foods such as CSB and bulgur, which are cooked in water, are not the best vehicles for delivering vitamin A. There is probably better vitamin A retention in wheat flour, which is made into bread. A better vehicle is vegetable oil when used as an ingredient in salad or at low or moderate cooking temperatures, so it makes good sense to have it fortified with vitamin A. The way most food companies address the problem of vitamin A losses is to simply add additional vitamin A to ensure that the surviving vitamin meets desired levels. This may not be the best approach with P.L. 480 commodities where economics is more of a constraint. Until a more stable form of vitamin A is developed, the best policy would be to keep fortifying all the P.L. 480 commodities at current vitamin A levels and grudgingly accept the fact that half of it will be lost during cooking.

## V. RECOMMENDATIONS & IMPLICATIONS

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### A. Meeting Micronutrient Levels During Production

#### **A1. Monitor and enforce minimum micronutrient specifications currently applicable to processed fortified P.L. 480 cereals.**

Fortified P.L. 480 processed foods, which do not include the blended foods CSB and WSB, have minimum, end-product fortification standards that are not being monitored or enforced by the USDA. These standards are similar to those for enriched cereals, under enforcement by the Federal (FDA) and state food regulatory agencies, except for the requirement of added vitamin A and calcium in Title II foods. The MAP activity uncovered a number of cases where fortified P.L. 480 food commodities failed to meet these minimum levels, particularly with vitamin A in wheat flour and bulgur.

Monitoring fortification levels in processed foods would involve the USDA FGIS testing a selected micronutrient indicator (discussed in Recommendation #A3) in all or some of the official lot samples and taking appropriate action if a producer was continually outside of specifications.

The direct cost of this monitoring is the cost of analytical testing. For a single vitamin A or niacin assay, this would cost \$50 per test of an FGIS lot sample<sup>10</sup>. For a two-railcar lot of 135 MT, this would cost \$0.37/MT, or about 5% of what it costs to fortify these commodities. There would be no additional sampling cost. While the USDA FGIS laboratory would perform this test, the cost of the testing would be reimbursed by the processing plant and reflected in their bid price, as is done under current procedures for other analytical testing. The cost would then be added to the cost of the commodity rather than have to be paid directly by the USDA. It would then proportionally reduce the amount of commodity that USAID could purchase, or a reduction of approximately 0.26%.

A secondary cost of this monitoring is any additional expense manufacturing plants would incur to ensure they conform to the standards. The MAP study revealed large differences between plants in their ability to meet specified minimum levels and maintain a uniform product. Enforcement of the micronutrient standards would motivate some plants to improve their operation and quality of the premixes they use. Investments in improvements by such plants might put them out of the competitive bid range. Some may choose to drop out of the program if they can not consistently meet the standards; others may have to be decertified by the USDA. This would reward those companies accomplished at fortification while penalizing those plants that were not. The end result may be a small increase in the average bid price of these commodities, since the low-cost producers would have increased costs or be fewer in number.

The MAP study showed that bulgur from one plant had one-quarter of the amount of vitamin A it was expected to have. Since the government was charged \$5.96/MT to fortify bulgur with vitamin A, for every MT of bulgur shipped, the government was incurring a loss of \$4.47/MT. Product monitoring in this case would have cost only \$0.37/MT to recover \$4.47/MT, a worthwhile investment.

The long term implication of monitoring and enforcement of current micronutrient standards would be to increase in amount of micronutrients, particularly vitamin A, actually delivered to food aid recipients. This should increase the nutritional health of the food aid recipients as regards vitamin A status, considered a major goal of the USAID. Implementation of such monitoring and enforcement should be possible by the end of 1999.

#### **A2. Establish, monitor and enforce a minimum, end-product vitamin standard for one vitamin and one mineral in fortified blended foods (CSB and WSB).**

Currently, the only regulations on the fortification of blended foods (CSB and WSB) are process standards in that they specify only the amounts of vitamins and minerals to be added to the commodity and not the levels in the final food. There are no minimum specifications for any of the micronutrients in the final blended food product, as there are for the fortified processed foods. There is no mechanism to ensure that the commodity has been properly fortified. The MAP activity revealed a couple of cases of low vitamin A levels in CSB while subsequent testing by the USDA showed many lots of CSB from some plants were low in a number of micronutrients including vitamin A.

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<sup>10</sup> Analytical test charges at the FGIS laboratory are \$50 for vitamin A, \$50 for niacin, \$15 for iron and \$20 for zinc.

USDA should use the current addition levels as the specification standards for all added micronutrients in blended foods, as given in Table 3. As described in Recommendation #A3, USDA should establish a minimum standard for one vitamin and one mineral as the micronutrient indicators, and monitor all lots using these vitamin and mineral "indicators" in order to ensure blended foods are properly fortified. This should result in shipped CSB lots being closer to target micronutrient levels along with improving the uniformity of micronutrient levels, providing more constant delivery of added micronutrients to the food aid recipients of blended foods.

With two tests, one for vitamins (vitamin A or niacin) and one for minerals (iron), the added cost would be \$65 per lot, or \$0.48/MT of CSB/WSB at 135 MT/lot. As with recommendation #A1, the added expense would be paid by the manufacturer and be reflected in a higher bid price for the commodity. This recommendation could be implemented by the end of 1999.

**A3. Establish vitamin A as the micronutrient indicator for all P.L. 480 processed fortified cereals. In processed fortified and blended foods (CSB and WSB), establish vitamin A as the vitamin indicator and iron as the mineral indicator.**

It would be costly and impractical to test for minimum specifications for all the micronutrients added to blended foods on a routine basis. A better approach would be to use one vitamin as an "indicator" to establish whether a product has been adequately fortified. Since this vitamin would be a component of a premix, and since the composition of the premix could be verifiable by independent means as described in recommendation #A5, compliance of a single vitamin indicator would indicate that fortification with the other vitamins and minerals added through the same premix was proper as well. Usually the most vulnerable vitamin is selected to assure that all nutrients meet established standards.

To arrive at the recommendation on indicators and allowable variation, the policies and practices of related industries were consulted. Infant formulas are under the regulations of 21CFR107 of the U.S. Food and Drug Regulations. This requires a certain minimum and, in some cases, a maximum level of specified micronutrients. The required practice is that every added micronutrient must be tested by the manufacturer and the FDA in every lot of product and must not be lower than 10% below the label claim. Nutrient indicators are not used in infant formulas since the level of each micronutrient is tested separately. To achieve the minimum, the manufacturer normally adds excess nutrient, while staying below any stated maximum.

Animal feed manufacturers do allow and use micronutrient indicators. These manufacturers also publish analytical variations (AV)<sup>11</sup> for each micronutrient and other feed components (5). AVs are guidelines for helping control officials make decisions on the acceptability of a product. Their AVs for the proposed indicators are: vitamin A  $\pm 30\%$ , niacin  $\pm 25\%$ , iron  $\pm 25\%$  and zinc  $\pm 20\%$ . Thus, corrective action would not normally be taken if a lot was within  $-30\%$  of the label claim.

Current U.S. regulations on the nutritional labeling of foods for human consumption under 21CFR also provide guidance on regulation for micronutrient fortification. The regulation states two classes of nutrients: class I, where the nutrient is added to a food and, class II, where the nutrient is naturally occurring in the food. If a nutrient is added, even though it is also naturally occurring, the nutrient is classified as class I. Since all nutrients under

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<sup>11</sup> According to the Association of American Feed Control Officials, Inc., Analytical Variations (AV's) are guidelines for helping control officials make routine decisions on acceptability of products appearing to be marginally acceptable. AV values are not intended to allow real deficiencies or excesses of the guaranteed ingredient. They are not intended to cover sloppy work, poor sampling, or any deficiency in analytical or clerical procedures. They allow only for the inherent variability in laboratory analyses. Manufacturing variations are not included in the AV values, which are generated from check sample data involving two determinations on separate days in a laboratory operating under normal working conditions. Replication of the assay will increase the analyst's confidence. However, replication in a laboratory only reduced the within-lab component of the total variance. Consensus of two or more independent laboratories reduces the between-lab variation, or bias. The between-lab variance is usually larger than the within-lab variance. The choice of using two coefficient of variation (COV) to determine the recommended AV is an arbitrary one. Using two CV means a 95% confidence limit. The risk of rejecting a satisfactory lot based on these AV's is one chance in 40. Assay values farther from guarantee will carry less risk. AV's are intended to apply to individual determinations made under routine conditions on a single sample. A history of seven or eight samples of a given product, each of which is found slightly deficient as much as the AV, is ample justification for the control official to take action.

consideration here are added nutrients, they would strictly be subject to the regulations governing class I nutrients. For all class I nutrients, the value for that nutrient should be at least equal to the label claim.

*(g)(4)(i) Class I vitamin, mineral, protein, dietary fiber, or potassium. The nutrient content of the composite is at least equal to the value for that nutrient declared on the label.*

The regulation for class II nutrients is the following.

*(g)(4)(ii) Class II vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium. The nutrient content of the composite is at least equal to 80 percent of the value for that nutrient declared on the label.*

**Under this regulatory climate, it would appear prudent and reasonable to set the minimum compliance standard at 80% of the added level for vitamin A,** which would allow for normal variability in sampling and the analytical method used to assay vitamin A.

Vitamin A is a most sensitive indicator because there is no vitamin A naturally present in these commodities; any vitamin A found could not be confused since no amounts are naturally present. Also FDA commonly used vitamin A because it is unstable, so when its level is in compliance the levels of more stable added vitamins are also likely to be in compliance. The standard also allows for normal variation due to sampling and testing. Vitamin A is an important micronutrient nutritionally, and also accounts for a large proportion of the cost of fortifying these commodities.

Since the minerals are added separately to CSB and WSB, a separate mineral indicator would be needed for the blended foods, unless a combined mineral/vitamin premix were allowed, as recommended in #B2 below. This would be a choice between iron and zinc. **Iron is recommended for use as a general indicator because of its nutritional importance and the advantage it has in being added to all fortified P.L. 480 food commodities, as opposed to zinc, which is added only to CSB and WSB.**

The minimum levels for iron, zinc or niacin, the other indicators investigated, should meet the target levels (100% of what is specified to be added), as given in Table 3. The large natural content of these three micronutrients in CSB and WSB provides a margin of error above the required level. They are also quite stable.

The indicator for the fortified processed P.L. 480 food commodities would be either vitamin A or iron, with the minimum standard the current minimum shown in Table 2 for the different class of foods. Only one micronutrient indicator need be tested since only one premix is used in these commodities (a combined vitamin/mineral premix). Vitamin A is recommended here as the indicator of choice as opposed to iron, for the same reasons discussed above. The minimum vitamin A level required in all fortified processed foods would be the current vitamin A minimum standard of 2205 IU/100g.

USAID and USDA have already started evaluating suitable micronutrient indicators through SUSTAIN's Food Aid Secretariat, as described in the Accomplishments Section. Four possible micronutrient candidates were selected jointly by USAID and USDA for the fortified blended foods (CSB and WSB), as shown in Table 19: vitamin A or niacin for the vitamin premix; zinc or iron for the mineral premix. A minimum vitamin A compliance minimum level of 1850 IU/100g was proposed because it is 80% of the current target and there is no vitamin A naturally present in these commodities. The 20% difference between the target and the minimum specification is in agreement with that used by the FDA, as described above. It allows for normal variation due to sampling and testing. The minimum levels for niacin, iron and zinc were taken at the target levels since there is a large natural content of these three micronutrients in CSB and WSB.

The natural content of these three micronutrients was not tested in the MAP study. However, results for niacin, shown in Figure 3, and for iron, in Figure 4, show that the levels of these two micronutrients in normally fortified products are well over the levels added, while vitamin A (Figure 1) and vitamin C (Figure 2) levels from these same plants are much closer to the added level. This difference results from the large natural content of these two micronutrients. Zinc was not tested in the MAP study, but it was tested in CSB by a separate USDA study (6) where high zinc levels similar to the iron levels found in MAP were found.

These four nutrients were selected by the USDA and USAID for a pilot evaluation as possible indicators due to their ease of assay and commonality in the different P.L. 480 fortified products. Some micronutrients are easy to analyze (vitamin C, pyridoxine) but are added only to blended foods. Other vitamins, such as folic acid, are added to all the fortified commodities but are very difficult to test for and as a result were not considered as possible indicators. A

relatively inexpensive nutrient, such as iron or thiamin, would be less desirable as a micronutrient indicator for a combined vitamin and mineral premix since it could be added in excess without incurring much additional cost, while allowing the more expensive nutrients, like vitamin A, to run low. very high, but somewhat variable, natural levels of niacin in CSB and WSB<sup>12</sup>. This study found that target niacin levels were easily achieved

There have been questions raised as to the appropriateness of niacin as an indicator because niacin levels were adequate even when vitamin A and vitamin C levels were low or marginal, as shown in Figure 3. There is no difference in the cost of running vitamin A and niacin assays, as charged by the FGIS laboratory. Both are run on the same equipment, a high-pressure liquid chromatograph (HPLC).

One concern with using vitamin A as an indicator, as suggested by the results of this study, is that it could be oxidized and lost during addition at the mill. Low levels of vitamin A would not necessarily indicate low levels of the more stable micronutrients that were added in a premix along with vitamin A. Loss of vitamin A during processing is a serious problem that the premix manufacturer and the processing plant can correct, as shown by the experience at one of the bulgur plants. Monitoring of vitamin A levels would encourage all plants to take similar corrective actions if loss of vitamin A was found to occur.

#### **A4. Remove all maximum standards on micronutrients and/or enforce minimum standards only in P.L. 480 processed cereals.**

Table 2 shows that some of the fortified processed P.L. food commodities have both minimum and maximum standards. A single minimum standard with overages left to “good manufacturing standards,” as used with wheat flour, is the preferred regulation by the FDA on micronutrients. Maximum levels serve no useful purpose. Manufacturers will not deliberately add excessive amounts of vitamins since it costs them money. There will be rare occasions when fortification will be high, but having a maximum level will not prevent that from happening.

This study showed that the current ranges are too narrow to be achievable. They are about the same size as the assay error, so it is unrealistic to expect manufacturers to stay within them. Removing the maximum or enforcement of the minimum only will save money by reducing the number of lots that would have to be rejected. If maximum standards are removed, some vigilance needs to be retained of any evidence that fat soluble vitamins or some minerals, such as iodine, are exceeding safe limits on a consistent basis.

#### **A5. Bulgur and wheat flour producers, especially, working with fortification premix producers, need to correct the problem with low vitamin A levels found in their commodities.**

This study showed a serious problem with low levels of vitamin A in bulgur and wheat flour at the point of manufacture. It is the responsibility of the mill, working with premix manufacturers, to take necessary steps to prevent this from happening. This might involve the mill taking the following actions:

- Request regular certificates of analysis (COV) on vitamin A activity in the premix lots, something not currently being provided by all premix manufacturers.
- The premix manufacturer should include an adequate overage of vitamin A that ensures it meets label claims within the stated shelf life of the premix.
- Maintain good storage of the premix to protect from heat.
- Use FIFO (first in, first out) inventory control and other logistical measures to ensure premixes are used within a month of receipt.
- Maintain feeders and associated equipment in good working order. Replace or repair worn feeders.
- Run daily check weights on feeders and adjust to product flow as necessary.
- Run regular premix inventory control and match against production figures to make sure the proper amount of premix is being used.
- Keep amount of air suction on product after it has been fortified to a minimum and check dust filters to make sure excessive levels of vitamins are not being removed. (This can be done with a UV light test for riboflavin.)

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<sup>12</sup> The niacin test proposed by the FGIS laboratory is for *free niacin*, which would eliminate some of the concerns in using niacin as an indicator. In that case the minimum niacin level should be set at 4.0 mg/100g or 80% of the level added.



There should not be any major costs incurred by the government in order for manufacturers to implement these suggestions. The result of such implementation would be that vitamin A levels in fortified P.L. 480 food commodities would meet or come closer to target levels allowing more vitamin A to be delivered to food aid recipients.

## **B. Meeting Micronutrient Uniformity at Production Level**

### **B1. Incorporate micronutrient fortification in the Total Quality Systems Audit (TQSA)**

USDA is current investigating utilizing a Total Quality Systems Audit (7) as a way to maintain quality in all P.L. 480 commodities. This would partly replace the final product testing system now in place. TQSA incorporates many of the quality principles and procedures in current use by the U.S. food industry. It focuses on the quality of the manufacturing process, rather than the finished product characteristics. TQSA places responsibility on the producers themselves to prove they have the capability of continually and consistently producing a quality product.

If the TQSA system is established, it should include auditing micronutrient fortification capabilities and practices. For example, in order for a plant to be certified to make fortified P.L. 480 commodities they would first have to demonstrate their ability to produce a quality, uniform product according to the procedures described in TQSA. They would be required to regularly monitor the composition and usage of the fortification premixes. TQSA is a reasonable and practical way to control and improve the poor plant uniformity within lots observed in this study by some of the producers. Inclusion of a micronutrient component in a TQSA program should not result in any additional cost.

### **B2. Consider allowing combined addition of vitamins and minerals to CSB and WSB.**

Current specifications require that a separate vitamin premix and mineral premix be added to blended foods (CSB/WSB) due to concern that the vitamins may not be stable when combined with certain minerals. There is no evidence that that is the case. Premix suppliers routinely mix vitamins and minerals with no degradation in shelf-life. The problem with having separate premixes for CSB/WSB is that some of the minerals are very fine in particle size (zinc sulfate, magnesium sulfate) and some are very coarse (sodium chloride, ferrous fumarate). The mineral (or salt) premix used to fortify CSB was observed to undergo physical separation during feeding in some plants. Another plant mixed the two premixes without a problem. There is no reason to require the two premixes be separate. Rather, it should be left up to the premix manufacturers and food producers to decide what micronutrients are best added as one premix, and which ones should be added separately.

This recommendation would not add an additional cost to blended foods fortification and could result in considerable savings. If iron and zinc were included in the vitamin premix, using vitamin A as an indicator would encompass those two minerals as well as all the vitamins. Implementation of this recommendation could result in lower costs and better uniformity of the micronutrients in CSB and WSB.

### **B3. USAID and USDA should help facilitate technical assistance to manufacturers of fortified P.L. 480 commodity producers on how to improve compliance and uniformity of micronutrient addition.**

The MAP study revealed a number of instances of poor compliance and uniformity in micronutrient fortification of P.L. 480 commodities. Some of the companies involved are large, technically astute operations, while others are smaller companies with limited experience in food fortification. All of these companies may benefit from the observations and lessons learned in the course of this activity. USAID could identify sources of technical expertise for plants requesting such assistance. This should allow improved uniformity and compliance to standards by all plants, regardless of size.

## **C. Improving Stability of Added Vitamins**

### **C1. Enforce the current stability specifications on the vitamin A required in fortified P.L. 480 commodities.**

The current stability specification on the type of vitamin A that must be used in fortified foods requires that it show no more than a 20% loss under specified conditions. The USDA should routinely request documented proof from the food producers that their vitamin premix suppliers are using vitamin A meeting the stability criteria. This could be done as part of the TQSA program in Recommendation #B1.

Such enforcement would not only restrict companies from using poor quality vitamin A, but would also reward those who have been using the higher quality material with better stability. Enforcement of this provision may also encourage development of new vitamin A products with higher stability, both in the dry product and during cooking.

The cost to the government in implementing this recommendation would be minimal. However, some companies currently using low cost vitamin A of inferior quality would have to use a more expensive product resulting in higher manufacturing costs that would be reflected in higher bids.

Implementation of this recommendation would result in lower vitamin A losses during manufacturing, shipping and storage of dry commodities, but probably would have little effect on improving the vitamin A retention during normal food preparation.

### **C2. Encourage mills and premix suppliers to improve vitamin A stability.**

Mills should work with their premix suppliers to establish how much, if any, vitamin A is being lost in their system. The FGIS test results shown in Tables 9 and 10 suggest significant losses of vitamin A in wheat flour and bulgur. If the amount of the loss is high, there are three possible approaches that could be taken:

- Use a different, more stable form of vitamin A.
- Add additional vitamin A to account for the loss. This can be done by changing the premix composition or increasing the addition rate of the premix.
- Change the conveying after addition of the vitamins from a pneumatic to a gravimetric system.

The cost of implementing these changes will vary from plant to plant with those plants with the most problems incurring the greater expense. This would be reflected in a somewhat higher bid price from those companies. Implementation of this recommendation would increase the amount of vitamin A delivered to food aid recipients.

### **C3. Continue fortifying processed and blended foods with vitamin A.**

The MAP study and related activities were instrumental in identifying specific losses of vitamins A and C due to cooking methods at distribution sites and in recipient homes. These losses were particularly marked in the preparation of gruels for weaning aged children. Despite the large loss of vitamin A found during normal food preparation procedures and the significant loss found in WSB after nine months of storage, it would be wise to continue the addition of vitamin A to these foods. The vitamin A remaining in the food as consumed is still of considerable benefit improving the nutritional health of millions of people.

Recognizing the reduced contribution of vitamin A from cooked processed and blended foods was one of the reasons vitamin A was added to refined, non-monetized, edible vegetable oil, as discussed in the Accomplishments section. This action, which was instituted December 1, 1998, helps ensure that recipients receive sufficient intake of this important nutrient from a P.L. 480 food basket despite the large cooking losses reported in this study.

### **C4. Investigate use of the more heat stable forms of vitamin A and C in CSB and WSB.**

The MAP and Vitamin C Pilot studies showed significant losses of vitamin A and C due to cooking methods at distribution sites and in recipient homes. These losses were particularly marked in the preparation of gruels for weaning aged children. The retention of vitamin C may be improved by using some of the more heat stable forms currently on the market, as discussed in the report on the Vitamin C Pilot study (8). These include products with better coatings that are more resistant to loss during cooking, but also the polyphosphate forms now being used in aquaculture. USAID should collect more information on these products and investigate their stability in CSB/WSB.

during storage and in conventional food preparation procedures. If the polyphosphate forms are found to be the most cost-effective, USAID should explore obtaining GRAS approval for these products so that they can be added to foods. The additional cost of using these new forms of vitamin C in CSB and WSB will range from \$0.50 to \$4.00 per MT of commodity. The result of using vitamin C sources with increased stability in cooking would be the delivery of more vitamin C to food aid recipients and a small improvement in iron absorption.

While identifying a more stable vitamin A source for possible use in Title II foods is not as promising as it is for vitamin C, USAID should investigate what is available, particularly in the area of better coatings and antioxidant systems that can provide better protection during dry storage and cooking.

**C5. Investigate precooked foods as an alternative means to deliver vitamin A and C to food aid recipients.**

Because of the substantial loss of vitamins A and C during normal cooking of CSB and WSB, USAID and USDA should investigate alternate food delivery systems where cooking is not required. This could include precooked foods such as biscuits that can be eaten without any food preparation, or an instant, fully gelatinized CSB that can be prepared into a gruel by simply mixing with water. Similar foods are already being distributed to food aid recipients by WFP and some PVOs, so the technology involved in production is already established. A major task would be to establish the acceptance and cost-effectiveness of having a high value-added, fortified food available through Title II. These new foods must come with guidance and careful monitoring of their use because of the constant threat of gastrointestinal disease epidemics in emergency situations when potable water is not readily available.

**C6. Include information on vitamin retention in the Commodity Reference Guide for use by field partners who provide food aid.**

Most PVOs and other agencies distributing P.L. 480 fortified foods do not take into account normal vitamin losses during cooking in calculating food rations. USAID should make micronutrient friendly preparation methods available to these groups, through the Commodity Reference Guide or other guidance. This information should allow users to better determine the levels of nutrients actually being consumed by recipients, and it should recommend means to improve retention in cooking based on this study. For example, users should be informed of the higher vitamin retentions found when CSB is used to make ugali, or other preparations that use less water, as opposed to dilute gruel.

## VI. ACCOMPLISHMENTS

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### A. Improvements in Fortification at the Manufacturing Plants

Prior to this study, both the FGIS and most plants producing fortified P.L. 480 commodities paid little attention to the vitamin and mineral fortification of the commodities. There had been no quantitative testing of the micronutrient levels in the FGIS sample. As a result there was no awareness of any problems with compliance or uniformity. The plants were very concerned with meeting stipulated regulations and specifications on these commodities, but not those regarding micronutrient content. Blended commodities such as CSB and WSB only have *process specifications* and USDA did not then have a micronutrient testing program in place to monitor micronutrient specifications. Most plant personnel were unaware of the critical importance the added vitamins and minerals in the commodities they were producing had on the recipients of the food. The SUSTAIN testing program heightened their awareness of the importance of micronutrients in the commodities and the need for improved quality control.

In the course of visiting these plants (with the full support and assistance of the FGIS), sampling the production and testing it for vitamins and minerals, most plant personnel and company management realized the need for application of the fortification premix correctly and uniformly. The process of sampling itself was an impetus for the plants to give more attention to what they were doing and to improve it where they could. The manufacturers of the vitamin and mineral premixes used to fortify these commodities were all informed of the MAP activity, and some were directly involved in providing premix assays and advising on plant fortification practices and problems. They would be an integral part of any continuing improvement process.

One example of this cooperation was the response by one manufacturer to serious problems found in the fortification of bulgur and soy fortified bulgur with vitamin A. The SUSTAIN testing detected both low values and a lack of uniformity for vitamin A in bulgur and soy-fortified bulgur. One bulgur producer (plant G) took a number of actions to solve this problem, including requesting and using a modified fortification premix. These actions resulted in considerable improvements in the final levels in the product. But there is still room for improvement since subsequent production continues to show low vitamin A content. Preliminary findings indicate that this could be due to oxidation although further testing would be needed to more fully determine the cause of the problem. The Quality Control Manager for the company owning bulgur plant L, which has the biggest problem in low vitamin A levels, was informed of the situation and is looking into possible solutions. The fact that USAID and USDA considered micronutrient levels important, as evidenced by their involvement in this study, was the trigger for plants to attempt to improve their fortification processes.

### Vitamin A Fortification of Refined Vegetable Oil Used in Title II Programs

Providing vitamin A to deficit populations is an important program goal of the USAID. Because the MAP study revealed inadequacies in the present fortification program with vitamin A fortified Title II commodities, the need for an additional delivery system for this essential nutrient became evident. As a result, SUSTAIN commissioned a paper (8) on fortifying vegetable oil with vitamin A, which recommended that Title II oil be fortified to a level of 60 to 75 IU/g. This proposal was endorsed by an expert panel and presented to USAID for approval. USDA subsequently issued a revised specification requiring that all refined vegetable oil be fortified with vitamin A, effective December 1, 1998.

### Maintenance of Vitamin C Levels in WSB and CSB

In 1996 Congress directed USAID to initiate a pilot program to increase the vitamin C content of blended Title II foods from 40 to 90 mg/100 g and report on the results. Since this issue related closely to the ongoing MAP research activities, SUSTAIN was commissioned to develop and conduct the pilot program (9), under a separate Cooperative Agreement with USAID's Global Programs, Field Support and Research Bureau, Center for Population, Health and Nutrition, Office of Health and Nutrition (G/PHN/HN). This involved setting up and monitoring special productions of CSB and WSB with enhanced levels of vitamin C, as proposed by the Senate and House Appropriations Committees, and evaluating those commodities at recipient sites overseas.

The protocol and results of this study were reviewed by a special *Committee on International Nutrition--Vitamin C in Food Aid Commodities* of the National Academy of Sciences (NAS), Institute of Medicine (IOM), which then provided recommendations to USAID on the advisability of increasing the vitamin C fortification levels of CSB and

WSB. The conclusion from this activity was that vitamin C levels in these commodities should not be increased as proposed, the current levels being adequate to prevent vitamin C deficiencies in food aid recipients (10). This resulted in a cost saving of approximately one million dollars annually.

## B. Contribution to Quality Assurance Procedures

The MAP and Vitamin C pilot studies identified a need to monitor and ensure that end product micronutrient standards are being achieved. It was concluded that reliable vitamin and/or mineral “indicators” needed to be established in order to determine whether a product had been properly fortified. Working with USDA and USAID through the newly formed International Food Aid Commodity Secretariat, SUSTAIN recommended possible indicators and minimum specifications for consideration, shown in the following Table 19.

These recommended indicators were adopted and led to a plan whereby the FGIS lab would establish analytical procedures and test the first lot of each contract for CSB from all the different producers for these four nutrients. This initial testing was completed in February 1999, and the results are being evaluated. These are official USDA samples made up of multiple samples collected during production of a single lot of 4 to 6 hours. Composite test samples will not detect variations from bag to bag – only whether average values meet the specification target. Upon completion of the evaluation of the results the agencies will determine which indicator(s) should be used and how they will be enforced.

**Table 19. Possible Minimum Levels of Possible Micronutrient Indicators for Processed Foods**

Micronutrient	Minimum	Units
Vitamin A	1850	IU/100g
Niacin	5.0	mg/100g
Iron	14.7	mg/100g
Zinc	4.0	mg/100g

## C. Enhanced Dialogue on Food Aid Commodities Initiated and Promoted Among Stakeholders

It became evident in the course of the MAP and Vitamin C pilot studies that there were a number of issues regarding the nutritional properties and quality of Title II, P.L. 480 commodities that necessitated continued cooperation and dialogue between USAID, USDA, the commodity manufacturers and the PVOs. Under a Cooperative Agreement with USAID/G/PHN/HN, and with funding from USAID/BHR/FFP, an International Food Aid Commodity Secretariat (IFACS) was established under SUSTAIN to address these issues. This Secretariat will continue working on solving problems uncovered in the MAP study along with investigating any new problems that come to light. Information dissemination regarding food aid commodities will be facilitated through the IFACS Commodity Reference Guide update and web page.

## D. Updating the Commodity Reference Guide (CRG)

The Commodity Reference Guide (CRG) provides useful technical and policy information to PVOs and other interested parties on Title II, P.L. 480 commodities. The CRG has not been updated for ten years and so contains some outdated information. SUSTAIN is updating the CRG as part of the Food Aid Secretariat using some of the information obtained through the MAP activity. An Internet web site, [www.info.gov/hum\\_response/crg/](http://www.info.gov/hum_response/crg/) is being developed. This resource will make CRG information easier to obtain and keep current.

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